

November 21, 2003

TO:

Federal Trade Commission
Office of the Secretary
Donald S. Clark
600 Pennsylvania Ave., NW
Washington, DC 20580

**RE: Comments Regarding Hearings on Health Care and Competition
Law and Policy**

FROM:

American Association of Nurse Anesthetists (AANA)
412 First Street, SE, Suite 12
Washington, DC 20003
202.484.8400
Contact: Frank Purcell, Director of Federal Government Affairs



November 20, 2003

Dr. Timothy Muris
Chairman
Federal Trade Commission
600 Pennsylvania Ave., N.W.
Washington, DC 20580

Dear Dr. Muris:

On behalf of the 30,000 members of the American Association of Nurse Anesthetists, I am happy to provide the Commission additional information in support of its joint FTC / DOJ Hearings on Healthcare Competition Law and Policy.

Though a portion of this material logically follows from the Commission's hearing of June 10, 2003, regarding quality, barriers to entry and consumer choice, it does speak to the whole scope of the joint hearings. The information we provide serves the Commission's interest in "initiatives to enhance quality of care and ensure the free-flow of information because such initiatives benefit patients," as you stated inaugurating the Commission's hearings in November 2001. We understand that the Commission already possesses a considerable past record on antitrust issues in anesthesia, from its previous healthcare hearings in the early 1990s. To update the record, therefore, we are pleased to provide the Commission select more recent literature on the market in anesthesia practice, anesthesia quality outcomes, and anticompetitive behavior in anesthesia care. Most notably, we enclose a market study of anesthesia practice provided by Dr. Jeffrey Bauer, a witness who testified before your panel June 10.

Additionally, we observe that Jerome Modell representing the American Society of Anesthesiologists (ASA) has posted to the Commission his letter of July 30, 2003. Stridently, it denounces the Commission's examining the costs associated with particular healthcare benefits as "ethically repugnant." Surely, the Commission recognizes such language seeks not to enlighten, but to end the conversation. Our experience is that illegal anticompetitive behaviors increase costs, restrict consumer choice and deny patients access to healthcare. Illegal anticompetitive behaviors in healthcare, and likewise unwarranted legal, regulatory and policy restrictions on nurse anesthesia practice, are doubly pernicious in that they yield in economic terms a "dead-weight loss" – utter waste of scarce resources that benefit neither patients nor the healthcare system, but rather enhance certain fortunes that resist being broken.

Modell's oral statement to the Commission June 10, 2003, further reveals several errors of fact. We select five for the Commission's attention.

He states the scope of practice conflict between anesthesiologists and nurse anesthetists "stems fundamentally from the AANA's position that nurse anesthetists are qualified by their training and experience to engage independently in the practice of medicine as it relates to anesthesia care... ." This assumes subscription to the notion that anesthesia is solely the practice of medicine, an ASA chestnut. Rather, it is the *ASA's opinion* that CRNA care is the practice of medicine. The evidence is that anesthesia is the practice of nursing when provided by a nurse anesthetist.

Second, he states 45 U.S. states require nurse anesthetists to collaborate with or be supervised by a physician. The answer is 20 U.S. states require physician supervision. We are reluctant to quantify the number that require collaboration, since terminology in this field widely varies, but it is certainly less than an additional 25 states.

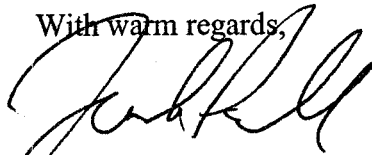
Third, he bases a "pattern" of state requirements for physician involvement upon a notion that legislators and regulators have determined that the delivery of anesthetics demands physician involvement to protect the patient. Lacking and failing to substantiate his statement with evidence in either the legislative record or anesthesia literature, his assertion is unsubstantiated.

Fourth, of the discredited Silber study upholding Modell's thesis, Silber coauthor Dr. David Longnecker MD states, "The study ... does not explore the role of (nurse anesthetists) in anesthesia practice, nor does it compare anesthesiologists versus nurse anesthetists." (Memorandum from Dr. Longnecker to CRNAs in University of Pennsylvania Health System's Department of Anesthesia, Oct. 5, 1998.)

Last, he states that since 1992 Medicare has applied "identical" supervision rules to CRNAs and to another type of provider, anesthesiologist assistants or AAs. This is false. CRNAs are eligible for direct reimbursement, with no supervision requirement included in CMS' Part B rules. AAs are not. Further, Medicare Part A requires AAs be medically directed by anesthesiologists, but makes no such requirement upon CRNAs.

Thank you again for your service to patients and healthcare providers alike by hosting such comprehensive hearings on healthcare and antitrust. If you have any further comments or questions, please contact me.

With warm regards,



Frank Purcell
Director, Federal Government Affairs

Cc: Tom McKibban CRNA MS, AANA President
Jeffery Beutler CRNA MA, AANA Executive Director

Attachments

Selected Literature on Anesthesia Markets, Quality Outcomes, and Responses to Anticompetitive Behaviors

Market literature on anesthesia practice

- Bauer J, "New Economic Perspectives on the Market for Anesthesia Services: Achieving Desired Reforms through Fair Competition," supplemental written testimony to the Federal Trade Commission, November 2003.
- Klein J, "When Will Managed Care Come to Anesthesia," *J Health Care Financ* 1997;23(3):62-86
- Gunn I, "Health educational costs, provider mix and healthcare reform: A case in point – nurse anesthetists and anesthesiologists," *AANA Journal* 1996;64(1):48-52

The literature on anesthesia care quality and comparative outcomes

- Pine M et al, "Surgical mortality and type of anesthesia provider," *AANA Journal* 2003;71(2):109-116. Pine finds that among CRNAs and physician anesthesiologists, "the type of anesthesia provider does not affect inpatient surgical mortality"
- Department of Health and Human Services HCFA, "Medicare and Medicaid programs; hospital conditions of participation: anesthesia services," 66 FR 4674, 1/18/2001, regarding physician supervision of nurse anesthetists. The agency stated, "We are acutely aware that ensuring patient safety and high quality patient outcomes are the principal considerations in regulating providers. There is no indication that physician supervision of a CRNA affects such outcomes." The final rule published later in 2001 ultimately permitting States to opt out of CMS' superfluous physician supervision requirement against nurse anesthetists took back not a single word of this evidence.
- Silber J et al, "Anesthesiologist direction and patient outcomes," *Anesthesiology* 2000;93:152-63. This is the discredited study cited by Modell; a summary of Pine's (2000) scientific critique of it follows
- Synopses of previous research, including the National Academy of Sciences (1977), Forrest (1980), Bechtholdt (1981), the Minnesota Department of Health (1994), and others

Policy literature on anesthesia and antitrust

- Stewart J, "Testimony on behalf of the American Association of Nurse Anesthetists before the House Judiciary Committee," June 22, 1999. A summary of nurse anesthesia weathering the anticompetitive behavior of anesthesiologists and organized medicine.
- Cromwell J, "Health professions substitution, a case study of anesthesia," U.S. Health Workforce Power Politics and Policy, Osterweis et al ed., Association of Academic Health Centers, 1996 Washington DC

FEDERAL TRADE COMMISSION
HEARINGS ON HEALTH CARE COMPETITION, LAW, AND POLICY

**New Economic Perspectives on the Market for Anesthesia Services:
Achieving Desired Reforms through Fair Competition**

November, 2003

Presented on behalf of the
American Association of Nurse Anesthetists

by

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The opinions expressed in this paper are those of the author. They do not necessarily reflect positions of Superior Consultant Company, Inc. or the American Association of Nurse Anesthetists.

Health economists have been using theoretical models and econometric tools to analyze medical care for approximately four decades. Their efforts have generated some interesting debates and have occasionally produced a consensus. Consequently, each decade can be characterized by a health reform movement based on the prevailing conventional wisdom of economics—federalization of health insurance for

seniors and the poor in the 1960s, regulation of capital investments in the 1970s, competition among providers in the 1980s, and managed care in the 1990s.

Unfortunately, the economic interventions used to support these efforts have not yielded enduring improvements in resource allocation or market performance. Health economists have yet to identify a meaningful mechanism for efficiency and transfer it successfully to public policy. Fortunately, the Federal Trade Commission (FTC) is exploring new economic perspectives on reducing expenditures, improving quality, or broadening access. Its search is appropriately focused on finding workable remedies for restraints on competition, harmful barriers to entry, and other limitations on the free flow of inputs to their most productive uses.

The FTC is taking a much-needed look at one of the most pernicious and unfair restraints of trade in the medical marketplace—the monopoly power that physicians use to deny patients' direct access to equally qualified, less-expensive clinicians. This paper explains the impact of physicians' anticompetitive behavior in the market for anesthesia services, and it exposes the false arguments that medical doctor anesthesiologists (MDA)¹ have perpetuated in order to control certified registered nurse anesthetists (CRNA). This paper also shows why consumers are harmed by unnecessary restrictions on CRNAs' right to practice without the supervision of an MDA under circumstances that can only be explained by anesthesiologists' desires to protect monopoly profits.

MONOPOLIZATION AND ITS COSTS

The administration of anesthetics to control pain during surgery was developed by nurses in the second half of the nineteenth century. Anesthesia was performed almost exclusively by nurses until physicians began using educational reforms and state

¹ Although *medical doctor anesthesiologist* is commonly abbreviated as MDA in discussions of this issue, it is potentially misleading. Not all anesthesiologists are licensed as medical doctors (MD). Some graduated from osteopathic medical schools, which grant the doctor of osteopathy (DO) degree. The DO and MD degrees are effectively equivalent for physicians who have specialized in anesthesiology, so both are encompassed under the terms *MDA* and *anesthesiologist* in this paper.

medical practice acts to establish control over non-physician practitioners in the early decades of the twentieth century.² Physicians like to argue that nurse anesthetists are encroaching on the practice of medicine. From the perspective of historical fact, the opposite is true. Physicians “medicalized” (i.e., stole) a nursing function in the 1930s and 1940s and then used their control of the health insurance system during the 1950s and 1960s to secure generous reimbursement for a service that had previously been provided quite charitably and well by nurses.

The legacy of this monopoly is expensive. Anesthesiologists earn more than twice as much as nurse anesthetists each year, but the two professions effectively provide the same services.³ The number of anesthesiologists and the number of nurse anesthetists is about the same. Consequently, proportional analysis of income shares shows that one-half of the anesthesia labor pool (i.e., anesthesiologists) earns at least two-thirds of the income. If anesthesiologists were paid at the rate of nurse anesthetists, then one-third or more of the money paid for anesthesia services—that is, one-half the income earned by anesthesiologists—is being allocated unproductively. It could be reallocated to a more productive use elsewhere in the health care delivery system. The economic value of anesthesiologists’ monopoly-protected income, one-third or more of the total spending each year on anesthesia services, is not trivial.

Anesthesiologists, of course, argue that their higher incomes are fully justified by qualitative differences between anesthesiologists and nurse anesthetists. These arguments would justify anesthesiologists’ higher income share if they were demonstrably true, but they are not. The following table summarizes the erroneous positions taken by anesthesiologists:

² The classic introductions to the development of physicians’ monopoly power are Rosemary Stevens American Medicine and the Public Interest (New Haven: Yale University Press, 1971) and Paul Starr The Social Transformation of American Medicine: The Rise of a Sovereign Profession and the Making of a Vast Industry (New York: Basic Books, 1982). Specific analysis of the development of medicine’s control over nurses is presented in Jeffrey C. Bauer Not What the Doctor Ordered (New York: McGraw-Hill, 1998).

³ Income data for anesthesiologists and nurse anesthetists are inherently imperfect, so a conservative approach is used in this analysis. According to some available figures, anesthesiologists actually earn closer to three times the income of nurse anesthetists. With a 3:1 ratio, the cost of market failure would be even greater than the economic harm described in this paper.

<i>False Arguments Used to Justify Higher Incomes for Anesthesiologists</i>

- | |
|--|
| <ol style="list-style-type: none">1. Anesthesiologists are better trained and more qualified than CRNAs.2. Anesthesiologists provide higher quality services than nurse anesthetists.3. Anesthesiologists should supervise nurse anesthetists to ensure quality.4. Anesthesiologists should be paid for supervising nurse anesthetists. |
|--|

The data do not support these arguments. Many anesthesiologists may believe them fervently and honorably, but an objective look at the evidence suggests that the real issue is protecting monopoly incomes. The following sections explore each of the false arguments to show why considerable sums are being wasted as a result of indefensible restraints on competition in the market for anesthesia services. The paper concludes with an analysis of the anticompetitive motivation behind anesthesiologists' current effort to replace nurse anesthetists with anesthesiology assistants.

TRAINING AND QUALIFICATIONS

Anesthesiologists argue that they are more qualified to administer anesthesia because they have more years of training. The position has some initial appeal, but it weakens considerably upon careful examination.

- Doctors claim superiority because they have been to medical school. However, nurses can claim with equal pride that they have been to nursing school. The debate ends in a draw because the length of training for the MD and BSN degrees is the same—four years. The curricula in medical and nursing schools are also equivalent, particularly in the pre-clinical (i.e., first two) years when students in both schools take the same basic sciences courses, often in the same classrooms. Doctors still like to claim they have more training because most of them received a BA or BS before entering medical school. However, pre-med undergraduate degrees are almost never related to patient care. The clinical training of nurses or doctors is the same upon entry into their respective graduate programs in anesthesia.

- Anesthesiologists claim to be more qualified because they have generally completed four-years of residency, in comparison with the two-year minimum training of nurse anesthetists. Medical residents spend more time in general clinical medicine in the first year and may work on complicated cases in the fourth year, but the core training in anesthesia is equivalent in length in both programs.⁴ Since no study has ever shown that four years are needed to become proficient in the administration of anesthesia, the extra years of residency arguably make little or no marginal contribution to actual qualifications. In addition, many anesthesiologists in practice today have completed only two-year residencies because adding years to medical residency programs is a relatively recent phenomenon. Anesthesiologists who posit superiority of four-year residencies to cast doubt on the qualifications of CRNAs are also demeaning the qualifications of many good MDAs who completed only two years of residency training.

Indeed, years of training are not a meaningful proxy for qualifications to administer anesthesia. Anesthesiologists should not be allowed to cite longer residency training as an economically meaningful justification for higher incomes. The science and technology of anesthesia are changing so fast that knowledge and skills gained only a few years ago in a four-year medical residency or a two-year CRNA program are likely to be obsolete. The key to competency is continuing education and recertification in the use of current equipment and anesthetic agents. Nurse anesthetists are required to recertify their competency every two years and to attend a minimum of 40 hours of continuing education each year. Anesthesiologists do not have recertification requirements, they do not need to be board-eligible or board-certified to practice, and they are not required to complete continuing education requirements in order to practice as anesthesiologists. The difference speaks for itself. Regardless of past education, nurse anesthetists are ahead of anesthesiologists in meeting the quality criterion that

⁴ Cromwell, J "Barriers to Achieving a Cost-Effective Workforce Mix: Lessons from Anesthesiology" *Journal of Health Politics, Policy, and Law* vol. 24(6), p. 1332.

matters most—keeping up with the advances in a fast-changing, high-tech clinical science.

QUALITY OF SERVICES

Anesthesiologists like to talk about research showing death rates are higher when anesthesia services are provided by nurse anesthetists alone. In their opinion, safety is compromised by independent practice of nurse anesthetists and enhanced by anesthesia care teams (ACT) under the supervision of an anesthesiologist. The discussion sections in a few articles have made inferences about practitioner-based differences in outcomes, but ***no published study has ever reported a scientifically defensible test of a hypothesis about a statistically significant difference (i.e., a difference greater than one that could be explained by chance) attributable to the anesthesia practitioner or the care delivery model.***⁵

The studies used by anesthesiologists to imply inferiority of nurse anesthetist care are irrelevant for several reasons, including:

- The data are too old to be relevant. Though published in the 1990s, the studies are predominantly based on data from the 1980s. Given dramatic improvements in the science and technology of anesthesia in the intervening years (see previous paragraph), differences that may or may not have existed ten to fifteen years ago are unlikely to be relevant today.⁶
- The studies are uncontrolled. No effort was made to isolate other variables that might explain practitioner-related differences, erroneously causing differences to be attributed to the practitioners.⁷

⁵ For a comprehensible and comprehensive review of the criteria for a good scientific study, see Bauer, JC Statistical Analysis for Decision-Makers in Health Care (New York: McGraw-Hill, 1996), Chapters 1-3.

⁶ The classic study of this genre is Silber, JH *et al* "Hospital and Patient Characteristics Associated with Death after Surgery: A Study of Adverse Occurrence and Failure to Rescue" *Medical Care* 30:615, 1992. Although cited often as "proof" of excess deaths attributable to nurse anesthetists, the article does not include any data whatsoever on care provided by nurse anesthetists. It has, sadly, assumed the power of urban myth.

⁷ The "Minnesota study" is often quoted to show that an increase in the number of anesthesiologists accounts for a decrease in anesthesia-related mortality, but the data in the study were not collected or

- The data are not valid measures of the purported purpose of the research. In particular, studies that allegedly show practitioner-related differences in outcomes do not include data from different practitioner groups. The conclusions are pure conjecture, if not outright fabrications.⁸

A prospective randomized controlled trial (RCT) would be needed to support any defensible conclusions about practitioner-based differences between outcomes. However, such a trial would be extraordinarily expensive and would require several years to conduct (during which time the underlying circumstances would almost certainly change). The extreme rarity of anesthesia-related problems would necessitate sample sizes of several hundred thousand cases to produce a sufficiently powerful test, and patients would have to be randomly assigned to anesthesiologists and nurse anesthetists.

Such a study is almost certainly unaffordable and infeasible. It is also unnecessary because two other approaches can be used to produce an acceptable estimator of any differences in quality of care. First, premiums for professional liability insurance are useful because the malpractice premiums of nurse anesthetists should be high and rising if their care were inferior. Actual experience is the opposite. Nurse anesthetists' premiums from the St. Paul Companies, the largest professional liability carrier at the time, declined 50% between 1988 and 2001. Second, nurse anesthetists meet the criteria that physicians have implicitly used for many years to justify their elite positions as "captain of the ship."⁹ On both these counts, nurse anesthetists are at least as qualified as anesthesiologists.

controlled for this purpose. See Abenstein, JP and MA Warner "Anesthesia Providers, Patient Outcomes, and Costs" *Anesthesia and Analgesia* 82:1273, 1996.

⁸ Another article authored by Silber *et al* (*Anesthesiology* 93:152 2000), known as the Pennsylvania study, is used to argue that supervision by anesthesiologists leads to better care. However, the data in the study do not meaningfully define the provider of anesthesia care, and deaths are measured for a full 30 days following surgery—a meaningless period because anesthesia-related deaths almost always occur in the first two postoperative days. The title of the article, "Anesthesiologist Direction and Patient Outcomes," is totally unrelated to the data used in the study.

⁹ See Bauer, JC Not What the Doctor Ordered (New York: McGraw-Hill, 1998), chapter 5, for an in-depth analysis of the seven foundations of the right to independent, unsupervised practice: 1) advanced education; 2) ongoing certification; 3) scientific base; 4) coherent clinical model; 5) professional liability; 6) professional ethic; and 7) quality assurance.

ANESTHESIOLOGIST SUPERVISION OF NURSE ANESTHETISTS

Serious questions about the quality of care provided by anesthesiologists are raised, perhaps unwittingly, in recent articles from the official monthly newsletter of the American Society of Anesthesiologists (ASA). Statements like the following implicitly contradict the assumption that anesthesiologist supervision assures top-quality care:

“For the safety of our patients, we realize that physicians must remain in charge of all aspects of medicine, including the delivery of anesthesia care. Although most nurse anesthetists, like *most anesthesiologists, have as their pre-eminent goal the provision of good clinical care for their patients*, the nurse anesthetists’ state and national organizations all too often appear to be fixated on the single issue of independent practice.”¹⁰

The phrase in italics [added for this paper] implicitly states that some anesthesiologists do not strive primarily for top-quality care, yet it appears in an article defending anesthesiologist-directed care teams. The article pointedly does not say that all anesthesiologists aspire to good care.

A more serious problem with the quality of anesthesiologists is revealed in an article by a leader of the American Board of Anesthesiology:

“In summary, because of low numbers of trainees and low written pass rates [varied from 61-71% from 1994 to 1998; 46% in 2000] during the late 1990s, the number of newly board-certified anesthesiologists who became available to enter the national workforce pool went from an annual high of 1,536 in 1997 to only 705 in 2001. ...this represents only half the number of new ABA diplomate anesthesiologists available annually five years earlier.”¹¹

How can anesthesiologists argue that nurse anesthetists must be supervised when half the recently trained anesthesiologists could not pass the profession’s own board examination in 2000? Perhaps anesthesiologists should devote their time and money to self-improvement rather than supervising nurse anesthetists. And the rest of us should

¹⁰ David C. Mackey, M.D. “Anesthesiology Assistants: A New Direction for the Anesthesia Care Team Begins to Accelerate (Finally!)” *ASA Newsletter* March 2003

¹¹ Kapur, PA “American Board of Anesthesiology Update” *ASA Newsletter* April 2003, p. 16

question the quality of supervision by the large number of anesthesiologists who fail to meet the quality standards of their own profession.

The total lack of scientifically acceptable research to justify supervision as a quality-control imperative is matched by a total lack of accurate data and valid studies to determine efficient levels of supervision. The quantity of supervision associated with least-cost production or output-maximization for anesthesia services of a specified quality has never been determined. Medicare follows a definition of supervision simplistically based on specified ratios of nurse anesthetists to anesthesiologists. This approach effectively defines what an anesthesiologist must do to be paid for supervision, but it is not based on any clinical or economic data.

"The TEFRA standards [that define seven criteria for medical direction of nurse anesthetists by anesthesiologists] were intended to preclude payments to anesthesiologists for very limited or "phantom" services that add no significant value. They were not intended to define the clinically appropriate or most cost-effective roles for the members of an ACT [anesthesia care team], nor have any studies been conducted to support such interpretation."¹²

Even if good scientific research had demonstrated a positive association between anesthesiologist supervision of nurse anesthetists and better clinical outcomes—which it has not—no studies have been performed to determine the CRNA:MDA ratio that produces desired performance. Medicare payment policy obviously improves anesthesiologist incomes, but it has never been shown to improve consumer welfare. The fees paid to anesthesiologists for supervising nurse anesthetists are not producing any demonstrable economic value and are, therefore, unnecessary. The supervisory fees produce nothing of economic or clinical value. They only help anesthesiologists earn more than twice as much as nurse anesthetists for the same productivity.

SUPPLY AND DEMAND FOR SERVICES AND ANESTHESIOLOGY ASSISTANTS

Organized anesthesiology's latest anticompetitive behavior is its effort to resurrect anesthesia assistants (AA) as substitutes for nurse anesthetists. A growing shortage of

¹²Klein, JD "When will Managed Care Come to Anesthesia?" *Journal of Health Care Finance* 23(3):67, Spring 1997

anesthesiology services is advanced by anesthesiologists as the primary reason for expanding the use of anesthesiology assistants, but the implied existence of a widening gap between supply and demand is based on erroneous reasoning. Anecdotes about cancelled surgery are cited as "proof" of the need for more anesthesia caregivers. However, no current and reliable data demonstrate that cancellations are due to a shortage of assistants for anesthesiologists to supervise.

Hospitals' financial problems and the shortage of RNs (specifically, operating room nurses) are far more likely explanations of cancelled operations. Even if the alleged shortage of anesthesia services is real, increasing the supply of AAs is not the only possible solution to the problem. The quickest and most efficient way to increase the supply of anesthesia services would be to have anesthesiologists spend all their time in direct patient care rather than in supervising nurse anesthetists who are perfectly capable of working on their own. Basic economic analysis shows that the supply of anesthesiologists taking care of patients could be increased immediately and at no extra cost by freeing anesthesiologists from unnecessary and unproductive supervision of nurse anesthetists. Anesthesiologists would, of course, need to continue supervising anesthesiology assistants because AAs are not qualified for independent practice, but the economic impact is trivial because anesthesiology assistants are only slightly more than one percent (1%) of the anesthesia work force (i.e., approximately 700 AAs, 30,000 MDAs, and 30,000 CRNAs) .

The AA solution is also illusory because the alleged need for additional anesthesia personnel is based on projections of existing volumes of surgery. However, most health futurists are now forecasting a relative decline in surgery as more drugs are developed to cure or prevent conditions (e.g., coronary artery disease, breast and prostate cancers, arthritic joints) that have been traditionally treated with surgery. Even if the number of surgeries were to increase, the number of AAs that could be trained would be very unlikely to grow at all. New AA programs would need to be created to complement the two in existence, but academic health centers (or any other academic institutions, for that matter) where AAs must be trained have no money to start new programs.

In conclusion, organized anesthesia's push for AAs is an action that can only be explained by a desire to maintain control over a market. It is not supported by any proof whatsoever of economic or clinical problems with nurse anesthetists. Even the language used to promote AAs reflects anesthesiologists' fixation on control. CRNAs and AAs were together classified as "dependent anesthesia providers" in a recent issue of the official monthly newsletter of the American Society of Anesthesiologists.¹³ Another article in the same issue bemoaned "the extender monopoly held by nurse anesthetists."¹⁴

The reference to nurse anesthetists as extenders totally misses the point of product and market concepts used for more than a century to measure the extent of competition in a marketplace. In the language of economic analysis of market performance, nurse anesthetists are acceptable substitutes for anesthesiologists. However, AAs are not acceptable substitutes for CRNAs. Organized anesthesiology's attempt to place nurse anesthetists in the same market as anesthesiology assistants is indefensible. To make the additional claim that nurse anesthetists have a monopoly in that market is ludicrous! By all appearances, anesthesiologists are trying to create and control a vertically integrated market. The net effect of this monopoly behavior is gross inefficiency—unnecessary and inflated expenditures on anesthesiologists' supervisory services when the same medical care can be provided just as well by unsupervised nurse anesthetists.

Nurse anesthetists compete with anesthesiologists, but the competition has not been fair because anesthesiologists have successfully promoted false arguments to protect their disproportionate share of the total income for anesthesia services. Nurse anesthetists are at least as qualified as anesthesiologists to practice without supervision in the defined scopes of practice for which they are trained. Anesthesiologists like to talk about extra lives being lost due to unsupervised practice by nurse anesthetists, but absolutely no scientific evidence exists to support the claim.

¹³ Neeld, JB Jr "Integrating Anesthesiologist Assistants into Anesthesia Care Team Practices" *ASA Newsletter* vol. 67(3) March 2003

¹⁴ Mackey, DC "AA: A New Direction for the Anesthesia Care Team Begins to Accelerate (Finally!)" *ASA Newsletter* vol. 67(3) March 2003

The harm of monopoly power in this market is not lost lives. The real harm is millions and millions of dollars paid to anesthesiologists for supervisory services that do not need to be performed. The Federal Trade Commission has an excellent opportunity and a statutory responsibility to restore competition to the market for anesthesia services by taking actions that end anesthesiologists' indefensible monopoly practices.

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When Will Managed Care Come to
Anesthesia?

John D. Klein

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When Will Managed Care Come to Anesthesia?

John D. Klein

Managed care has begun to reshape many areas of health care practice, but anesthesia is not yet among them. The economics of anesthesia care are characterized by widespread inefficiency in the allocation of labor, and a unique market structure that poses special challenges to managed care influence. The potential for savings is great, perhaps as much as a one percent decrease in commercial health care costs. But these savings can only be realized if managed care organizations are able to restructure the incentives facing anesthesia professionals to promote innovation, cooperation, and shared benefits of efficiency improvements. Key words: *anesthesia, cost analysis, efficiency, labor, managed care, productivity*

The Anesthesia Market

In the late decades of the nineteenth century, the foundation for modern surgery was created with the development of anesthetic agents and techniques, together with a new understanding of the importance of sterile procedures.^{1,2} Today, as then, the primary activity of anesthesia is administering drugs or gases to render patients insensitive to pain during and after surgery.³

Almost all anesthesia services in the United States are provided by physicians or nurses with advanced training in the field—anesthesiologists and certified registered nurse anesthetists (CRNAs). The numbers of practicing anesthesiologists and CRNAs are very similar: approximately 24,200 anesthesiologists,⁴ and 23,800 CRNAs.⁵ As of 1994, median anesthesiologist earnings were \$244,600, or three times median CRNA earnings of \$82,000.⁶ For both professionals, incomes may vary significantly depending on experience, practice setting, and region of the country.

In many rural hospitals and in specialized

outpatient surgical facilities such as eye, dental, or plastic surgery, CRNAs are the sole providers of anesthesia services. In urban hospitals anesthesiologists may be the sole anesthesia providers, but the most common practice arrangement is an "anesthesia care team" (ACT) involving both CRNAs and anesthesiologists.⁷ In ACT settings, CRNAs are in constant attendance with the patient and perform the majority of anesthetic procedures, while anesthesiologists concurrently supervise the progress of from two to four cases and are personally involved at key stages, such as anesthesia induction and emergence.

John D. Klein is Vice President of the Health Strategies Group, Inc., in St. Paul, Minnesota.

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CRNA practice laws often refer to practicing "under the supervision" of the attending physician, and surgeons naturally work closely with the anesthesia staff. However, surgeons do not generally have comparable expertise to select anesthetic agents and to personally perform or direct anesthetic procedures (excepting local anesthesia). Accordingly, anesthesiologists and CRNAs generally assume primary responsibility for anesthesia outcomes whether in an ACT or independent practice setting.⁸ For both types of anesthesia providers the overall safety and outcomes record is very good⁹ and is reflected in declining malpractice insurance rates.^{10,11}

Most anesthesiologists practice through professional corporations that have exclusive practice privileges at specific hospitals or surgical centers, which may or may not be formalized through facility contracts.¹² A relatively small number of anesthesiologists are salaried as hospital or clinic employees. By contrast, 42 percent of CRNAs are hospital or university employees; one-third are part of an anesthesiologist/CRNA group; and one-fifth are either self-employed, part of a CRNA-only or temporary service (locum tenens) group practice, or based at a clinic.¹³

Anesthesia services account for a significant share of total health care expenditures. For commercial group health insurance (employment-based), anesthesia services account for approximately 2.4 percent of total health care costs.¹⁴ For Medicare, the percentage is approximately half as large, due mainly to much lower rates of reimbursement than commercial payers. Medicare also differs from commercial payers by reimbursing anesthesiologists and CRNAs at comparable levels.

Although beyond the scope of this article, anesthetic drugs, supplies, and equipment

are also a significant part of anesthesia-related health care expenditures. The combined cost of anesthesia labor, drugs, supplies, and equipment has been estimated at three to five percent of total health care expenditures.¹⁵ To put these costs in perspective, all U.S. health expenditures for home health care, durable medical equipment, and vision products combined represent three percent of the total, while expenditures for drugs and nondurable medical equipment are eight percent.¹⁶

Barriers to Competition

Many economists and health care analysts believe that unjustified limits on competition among various classes of health care providers are one of the primary sources of health care market failure. In describing the evolution of the division of health care labor in the 1920s and 1930s, Paul Starr writes: "Had medical care become a corporate enterprise, the medical care firm (even if run by doctors) would have had an incentive to seek greater flexibility in its use of personnel. It might have tried to substitute the cheaper labor of ancillary workers for physicians in many areas that physicians insisted on retaining."^{17(p.225)}

While the precise degree to which anesthesiologists and CRNAs are substitutes is inherently controversial, there is widespread agreement in state licensing rules and anesthesia market studies¹⁸ that the overlap in scope and quality of practice is substantial. Given the large gap in earnings, it seems reasonable to conclude that CRNAs are more cost-effective providers of anesthesia care. One might expect, therefore, that since managed care enterprises now have increasing influence in the health care market, they will aggressively explore opportunities to expand

Even highly integrated health plans have done little to restructure the allocation of labor in anesthesia.

CRNAs' role, while maintaining high standards of quality.

In fact, this has not yet occurred to any significant degree. Even highly integrated health plans, such as Kaiser Permanente of California, have done little to restructure the allocation of labor in anesthesia, despite having identified significant internal opportunities for improvement through increased use of CRNAs.¹⁹ Why has managed care not done more to improve the efficiency of anesthesia services, and what are the barriers to doing so?

Evolution of the anesthesia labor market

In current discussions about expanding the role of advanced practice nurses (APNs), especially in primary care, a common topic is legal barriers APNs face in their permitted scope of practice, specifically in performing tasks that might otherwise be performed by physicians.^{20,21} Compared to other APNs, CRNAs have already achieved substantial practice authority. Although CRNAs still face a variety of practice barriers in some facilities and health plans, they can and do serve as the exclusive provider for the full range of anesthesia services at hospitals and ambulatory surgical facilities, and receive direct reimbursement from Medicare and many health plans.

CRNAs' practice status arises from their evolution as "the original APNs." During the early stages of modern surgery development in the late nineteenth century, surgeons en-

countered a shortage of skilled and disciplined anesthetists. Anesthesia fees were negligible, and other specialties were more attractive to medical students. A solution was found by training religious order nurses to serve as anesthesia specialists. Nurse anesthetists contributed significantly to the early research in the field, and over time nurse anesthesia schools were established and CRNAs became the most common providers of anesthesia care.²²

The demand for anesthesiologists and CRNAs is closely related. In most states, a supply of CRNAs per capita in excess of the national median coincides with a supply of anesthesiologists below the median, and conversely. A 1990 report by the U.S. Department of Health and Human Services noted that, "the substitutability of CRNAs for anesthesiologists is demonstrated in the geographic distribution of the two providers."^{23(p.20)}

For most of this century, the demand for anesthesia professionals has exceeded supply, fueled by growth of the population and surgical capacity. In this environment, tensions between anesthesiologists and CRNAs over professional status and the division of labor have been mitigated by the common effects of a rising tide. There are abundant signs, however, that the tide has turned. While the long-term demand for anesthesia labor is expected to grow, the current supply appears to exceed the demand, particularly for anesthesiologists.

Only in recent years did the number of anesthesiologists approach the number of CRNAs. In 1967, there were still fewer than 8,000 practicing anesthesiologists compared with over 13,000 CRNAs.²⁴ Since 1967, the number of practicing CRNAs has increased 78 percent, while the number of practicing anesthesiologists has increased 208 percent.

Interest in anesthesiology has been fueled by increasing income levels, and its status as one of the highest-paid medical specialties. Anesthesiologist incomes have been enhanced by the widespread adoption of the ACT practice model, which allows anesthesiologists to bill for their role in multiple concurrent cases.

In recent years, however, anesthesiologist salaries have leveled off,²⁵ and the number of medical students entering anesthesiology residencies has dropped 55 percent since 1991.²⁶ The *Wall Street Journal* reported that one recent graduate had received only one full-time offer after six months of looking, and for less than half what other partners were making.²⁷ A recent study commissioned by the American Society of Anesthesiologists explored a number of alternative scenarios for predicting the future demand for anesthesiologists, including "physician-intensive" and "CRNA-intensive" scenarios, in recognition of the many "activities of CRNAs in which there is substantial overlap with anesthesiologists."^{28(p.iv)} The study concluded that "the number of residents enrolled in four-year programs needed to meet future requirements will decrease under all scenarios."^{29(p.xvi)} Under the CRNA-intensive scenario, the number of anesthesiologists now in practice exceeds the number of anesthesiologists projected to be required by almost two to one.

Given these findings, it is not surprising that overall tensions between CRNAs and anesthesiologists are growing. Relations between the respective professional associations are sufficiently frosty that formal dialogue of any type has been rare, due in part to anesthesiologists' long-standing insistence—rejected by CRNAs—that CRNAs accept the anesthesiologists' 1982 statement on the roles of anesthesiologists and CRNAs

within ACTs.³⁰ Further adding to tensions are specific efforts by anesthesiologists to increase job opportunities at CRNAs' expense, such as

- Working to increase anesthesia practice opportunities for professionals who can practice only under anesthesiologist supervision, such as physician assistants and anesthesia technicians.³¹ (CRNAs are not required to practice under anesthesiologist supervision.)
- Calling for the direct replacement of CRNAs by anesthesiologists. The treasurer of the American Society of Anesthesiologists recently wrote, "The simple fact is there are more than enough positions for every qualified resident; they exist in the [anesthesia] care team and are currently held by anesthesiologists [CRNAs]."^{32(p.3)}
- And (according to a still-pending federal antitrust lawsuit filed by the Minnesota Association of Nurse Anesthetists) conspiring to eliminate CRNAs as lower-cost competitors.³³

Role of hospitals in limiting efficiency improvements

Historically, hospitals have been strong supporters of CRNAs. It was the American Hospital Association, rather than the American Nurses Association, that came forward in 1931 to sponsor creation of the American Association of Nurse Anesthetists.³⁴ CRNAs have played a crucial role in allowing hospitals to meet increasing demand for surgery, and hospital employment remains most common for CRNAs. However, the changing economics of the health care market have tended to undermine some hospitals' allegiance to CRNAs, and the market forces

affecting hospitals have generally precluded them from being agents of change to promote efficiency in the anesthesia labor market.

With the increasing replacement of fee-for-service reimbursement with diagnosis related groups (DRGs), capitation, and other forms of fixed or bundled prices, hospitals' financial incentives have shifted from providing services to controlling costs. For many hospitals, CRNAs are among the highest-paid employees, and a primary candidate for cost containment scrutiny. To the extent that hospitals' managed care contracts do not fully reflect CRNA costs, and managed care contract negotiators do not fully appreciate that element of hospitals' cost structure, reducing CRNA "overhead" can provide hospitals with an opportunity to substantially improve their profit or surplus margin.

The most common way for hospitals to reduce CRNA overhead is by shifting CRNAs to independent contractor status, most often as subcontractors or employees of the anesthesiologist group. Since hospitals usually have no overall accountability for anesthesia costs, it does not affect their economic circumstances if total anesthesia costs rise through diminished use of CRNAs. Although hospitals provide the space, drugs, materials, and patients for anesthesiologists to practice, anesthesiologist charges are entirely separate from hospitals' billing stream and cost structure. (The same is true for independently billing CRNA groups.) Anesthesiologist groups, for their part, naturally seek to maximize their income and job security, and if given increased authority to control and direct use of the CRNA "resource," are likely to exercise it with this objective.³⁵ In other words, hospitals' efforts to cut costs in response to managed care pressures can have the effect of placing authority to decide

The federal Medicare program has taken greater interest in anesthesia costs than any other major health care purchaser.

anesthesiologist and CRNA allocations solely in the hands of anesthesiologists, who have a direct economic stake in the decision.

Even in cases where a hospital may be considering increasing its use of CRNAs, the centrality of physicians to hospitals' economic well-being and governance makes it very difficult to upset the apple cart. A hospital's patients are referred or admitted by physicians; formal physician-hospital organizations are central to many hospitals' marketing efforts; hospitals' bylaws and medical staff standards systematically favor physicians over nonphysicians; and anesthesiologists are part of the community of physicians, while CRNAs are not. In hospitals that use ACTs, the anesthesia department is most often (although not always) headed by an anesthesiologist. In the environment of most hospitals, anesthesiologists have many advantages over CRNAs in their ability to limit competition, or to mitigate the impact of any changes in the division of labor that may affect anesthesiologists negatively.

Hospitals' incentives regarding the mix of anesthesia labor may change significantly if DRG or other bundled-service payment methods are revised to incorporate all anesthesia costs, including the costs of anesthesiologist services that are now billed independently. While some payers, including Medicare, have begun to experiment with such payment methods, they have yet to be adopted on a large scale.

Role of Medicare in limiting efficiency improvements

The federal Medicare program has taken greater interest in anesthesia costs than any other major health care purchaser. The U.S. General Accounting Office has issued a series of reports concluding that Medicare has overpaid for anesthesia services, and recommended a variety of cost-cutting steps that have led to changes in Medicare reimbursement policy.³⁶ While these steps have been effective in reducing Medicare anesthesia costs, their impact on the efficiency of the anesthesia labor market has been mixed.

Medicare's primary approach to anesthesia cost containment is aggressive price discounting. Whereas a health maintenance organization (HMO) or preferred provider organization (PPO) may seek anesthesia cost discounts of from 15 to 30 percent from billed charges, Medicare's mandated discounts are generally in the range of 60 to 70 percent. A recent study commissioned by the American Society of Anesthesiologists concluded that an anesthesiologist working exclusively on Medicare patients would earn a net income of \$53,769, the lowest of any non-primary care specialty, and only 22 percent of the median income for all anesthesiologists.³⁷

While low price levels have made Medicare business less financially rewarding to all anesthesia providers, other Medicare policies have had the effect of limiting opportunities to expand the use of lower-cost CRNAs.

TEFRA reimbursement standards

As part of the 1982 Tax Equity and Fiscal Responsibility Act (TEFRA), Pub. L. No. 97-248, Medicare instituted seven prerequi-

sites for anesthesiologist "medical direction" billing in an ACT setting, including performing the preanesthesia evaluation, participating personally in the most demanding procedures, and remaining physically present and available for emergencies. These requirements were intended to curb the practice of anesthesiologists billing for medical direction despite minimal participation in a case.³⁸

Prior to TEFRA, there had been no effective limit on the number of concurrent cases for which anesthesiologists could bill for providing medical direction and no definition for what constituted significant participation in a case. The TEFRA standards were intended to preclude payments to anesthesiologists for very limited or "phantom" services that add no significant value. They were not intended to define the clinically appropriate or most cost-effective roles for the members of an ACT nor have any studies been conducted to support such an interpretation.

Nevertheless, many anesthesiologists have advanced an interpretation of the TEFRA standards as quality guidelines and as an implicit federal government endorsement of anesthesiologists' role within ACTs. To the extent that anesthesiologists have been successful in advancing this interpretation with hospital administrators or other persons in positions to influence the design of anesthesia practice, the TEFRA standards have had the unintended effect of limiting exploration and assessment of alternative ACT models that may be superior in terms of clinical and efficiency outcomes.

ACT payment reform

More recently, the 1993 Omnibus Budget Reconciliation Act (OBRA) legislation instituted a phased-in reduction in the amount

Medicare will pay for medical direction in an ACT setting, and a fixed 50:50 split in the ACT fee between anesthesiologists and CRNAs. In the past, Medicare has paid more for cases in an ACT setting than for cases performed by an anesthesiologist or CRNA alone. Under OBRA, Medicare ACT reimbursement will be reduced from 120 percent of the fee for an anesthesiologist practicing alone in 1994, to 100 percent of the anesthesiologist-only fee in 1998. While these reforms will certainly lower Medicare costs, they create three problems for promoting the efficient use of labor:

1. They rigidly divide payment 50:50 between anesthesiologists and CRNAs, despite the fact that in many practice settings, especially those with three or four CRNAs for each anesthesiologist, CRNAs contribute substantially more labor.
2. They establish anesthesiologists doing cases solo as the reimbursement standard for all anesthesia delivery, irrespective of whether it is most efficient and appropriate to have ACTs, solo anesthesiologists, or solo CRNAs.
3. Paying no more for ACTs than solo practitioners implies that ACTs provide no added value in terms of patient care and removes the economic incentive to explore whether there are, in fact, options for using anesthesiologists and CRNAs together that are cost effective and quality enhancing.

Two-provider cases

Medicare's implicit skepticism about the value of ACTs is also evidenced by its policy with respect to cases where one anesthesiologist and one CRNA are both continually present. For such 1:1 cases, Medicare's gen-

eral policy is to pay only for the anesthesiologist, on the broad presumption that it is not necessary to have multiple providers continually present. For CRNAs employed by hospitals, this means that such cases return no revenue to the hospital. And for CRNAs generally, this means that complex cases for which a 1:1 ratio may be clinically appropriate are not economically feasible, at least for Medicare patients. As part of the negotiations over the 1996 federal budget, Medicare has agreed to reform its 1:1 policy to split fees between anesthesiologists and CRNAs as they do for other ACT cases. For now, however, Medicare payments in 1:1 cases continue to flow only to anesthesiologists.

Medicare has instituted some changes that enhance CRNAs' market position. Medicare allows CRNAs to bill directly for their services, a precedent that has helped to persuade some health plans to follow suit. By paying anesthesiologists and CRNAs at the same level for most services, Medicare reinforces the overall parity and substitutability of the two classes of providers. But on the whole, Medicare's approach to anesthesia cost containment may be characterized as "brute force fee cutting," without becoming particularly involved in "where the chips fall" or in reengineering how care is actually delivered. While Medicare's TEFRA and OBRA reforms have successfully lowered anesthesia costs, they appear also to have had the unintended effect of reinforcing anesthesiologists' role and limiting the incentives and flexibility for exploring new divisions of labor.

Limited impact from managed care in promoting efficiency improvements

As with Medicare, HMOs and other managed care organizations would benefit di-

rectly from reducing anesthesia costs while maintaining or enhancing the quality of care. But few managed care organizations have advanced beyond relatively modest fee discounting in influencing the anesthesia market or have made substantive efforts to evaluate and redesign the anesthesia production function. Why is it that managed care organizations have not made greater efforts to determine the optimal allocation of anesthesia personnel? The answer lies in the following five factors:

1. Anesthesia is "packaged" with the hospital contracting decision.
2. Anesthesia efficiency is a complicated area to attempt to improve.
3. Anesthesia billing methods are confusing and create inappropriate incentives.
4. There has been little competitive pressure to improve anesthesia efficiency.
5. There has been little research into how to improve anesthesia efficiency.

Anesthesia is "packaged" with the hospital contracting decision

The two things any HMO or PPO must have in their provider networks are hospitals and primary care physicians, and it is these contracts that typically receive the greatest attention. Health plans must ensure adequate geographic coverage of their service area and inclusion of the hospitals most used by the plan's physicians. Health plans may have greater flexibility and leverage in contracting with non-primary care physicians—except for physicians who have exclusive practice rights at specific hospitals, such as anesthesiologists.

Once a health plan has decided to contract with a hospital, the facility's preexisting arrangements for anesthesia care are automati-

cally part of the "package." Under these circumstances, the health plan has very limited leverage for negotiating favorable terms with the established anesthesiologist group, or for advancing proposals for alternative and potentially more cost-effective anesthesia practice models. In most cases, health plans are likely to be content with negotiating some degree of discount, while deferring to hospitals their established role of determining anesthesia practice arrangements. Given that hospitals are not directly accountable for anesthesiologist costs, they are unlikely to aggressively seek out more efficient arrangements without strong incentives and involvement from the health plans.

Anesthesia efficiency is a complicated area to attempt to improve

It is natural for health plans to seek out savings that are relatively easy to achieve before moving on to more challenging areas. For example, health plans have been very aggressive in reducing unnecessary hospital days, for which specific incentives can be readily targeted, yielding substantial savings in total health care expenditures.³⁹ By contrast, anesthesia is a complicated area, providers are often well entrenched and resistant to change, and there are no "easy pickings" in terms of managed care savings.

The degree of difficulty does not necessarily change with the degree of vertical integration. Health plans that own or exert substantial market control over their hospitals and clinics, such as staff model HMOs, may face many of the same issues of a physician-dominated organizational culture as hospitals. Replacing physicians with APNs or other less expensive providers may be efficient, but may lead to widespread dissatisfaction and resistance among the health plan's

community of physicians. At the other end of the integration continuum, health plans that command only a fraction of the market share at any given hospital cannot reasonably challenge a hospital to redesign itself to their specifications—even assuming the health plan knew enough about anesthesia to want to do so.

Anesthesia billing methods are confusing and create inappropriate incentives

A third factor limiting the influence of managed care in anesthesia is confusion and inappropriate incentives associated with anesthesia billing methods. Fee-for-service anesthesia is billed on the basis of a unique methodology that measures total units per case, including time units and base units. Time units reflect the duration of the procedure and are usually charged at the rate of one time unit for each 15 minutes. Base units reflect the complexity of the surgical procedure and may range from 3 or 4 for simple procedures, to 20 or more for highly complex procedures.

One shortcoming of this system is that although surgical complexity is certainly related to anesthesia complexity, other factors such as the patient's health may be better predictors of anesthesia complexity and required resources.⁴⁰⁻⁴² For example, a complex procedure performed on a healthy patient may require less demanding anesthesia services than a simpler procedure performed on a patient in poor health. Base units defined only in terms of surgical complexity have significant shortcomings as a mechanism for appropriately reimbursing anesthesia services.

Another shortcoming of the complex anesthesia billing methodology is the difficulty

of recognizing the separate contributions of anesthesiologists and CRNAs in ACT settings. Medicare recognizes the two provider classes and, except for 1:1 cases, will pay each provider separately for the units associated with a particular case. Commercial health plans, by contrast, will rarely "pay twice" for anesthesia by reimbursing separate bills from anesthesiologists and CRNAs (or from hospitals on CRNAs' behalf) associated with the same case, taking the view that once they've paid one anesthesia bill, they should not have to face another one. This is not a problem for anesthesiologists and CRNAs practicing as sole anesthesia providers for a given facility or case, but can be a serious problem for ACT practitioners.

If CRNAs are working as anesthesiologists' employees or subcontractors, the anesthesiologists' bill will cover the CRNAs. In regions of the country where this is common, unit billing rates tend to be higher to reflect the combined anesthesiologist/CRNA cost structure. In areas where CRNAs are more likely to be hospital employees, however, there is no single bill that incorporates both anesthesiologist and CRNA costs. Because anesthesiologists bill separately from hospitals and for anesthesia services only, they generally bill more quickly and effectively. Health plans will reimburse the first-arriving anesthesiologist bill, but not a separate and later-arriving CRNA bill.

Because of health plan resistance, rather than billing for CRNA services on a fee-for-service basis, hospitals may seek to recover their CRNA costs through managed care fees on a DRG, per diem, or other bundled-service basis. This approach may not work, however, with indemnity carriers who must be billed on a fee-for-service basis. And by

placing less emphasis on aggressive fee-for-service billing for CRNA services, hospitals are also likely to recover less from Medicare or other government programs that do accept separate CRNA bills. The overall impact of this billing environment is difficulty for hospitals in recovering CRNA costs and a further impetus to remove CRNAs from the hospital payroll, even if the result is a net increase in total anesthesia costs.

There has been little competitive pressure to improve anesthesia efficiency

A fourth factor limiting the influence of managed care in anesthesia is the simple fact that, to date, there is little direct competition to do so. Once one HMO in a market area begins to lower its premiums by reducing the average hospital stay, other HMOs must follow suit or risk becoming uncompetitive. But if all health plans are allowing hospital stays of the same duration as 20 years ago, there is much less urgency for any health plan to worry about lengths of stay. Anesthesia efficiency today is much like lengths of stay 20 years ago—the potential for improvement is there, but remains largely uninvestigated.

If this is to change, competitive pressure may have to be consciously applied from the outside by health care purchasers. The impact of Medicare has already been discussed. Other potential sources of pressure are large employers and multiemployer purchasing coalitions. Through the use of health plan report cards and targeted contractual incentives, some purchasers are becoming more aggressive and sophisticated in pressuring health plans to improve performance in certain areas. Anesthesia is not yet among these, however. Even the radical approach adopted in the recent request for proposal by the Twin

Cities Buyers Health Care Action Group, with its goal of replacing traditional HMOs with new “care systems” dedicated to innovation and quality improvement, offers few degrees of freedom for care systems that may be inclined to innovate in the area of anesthesia efficiency.⁴³

There has been little research into how to improve anesthesia

And last but not least, there is the problem of inadequate research into how the efficiency of anesthesia may be improved. A recent survey of the anesthesia literature found that “only 2% of clinical investigations and 1% of scientific abstracts included any useful cost information.”^{44(p.840)} Almost all anesthesia research literature that addresses costs is limited to the evaluation of specific anesthetic drugs, agents, and supplies.⁴⁵ While these costs are significant and an area where substantial improvement could occur, anesthesia labor is the area of greatest potential gain.⁴⁶⁻⁴⁸

Managed care organizations have begun to closely evaluate practice pattern variations in areas such as elective surgery, diagnostic procedures, and the treatment of specific conditions. The study of variations provides a basis for investigating whether certain providers may be providing more or less care than is appropriate, and for developing guidelines to assist providers to treat patients as effectively and efficiently as possible. In its own way, anesthesia delivery, and the ACTs in particular, exhibit just as much practice variation as elective surgeries, and with equally significant cost implications, but have not received comparable managed care attention.

Despite the prevalence of ACTs, there is

no consistent standard or model of ACT structure and function. From region to region, and from hospital to hospital within specific communities, there is wide variation in ACT division of labor, the roles and responsibilities of anesthesiologists and CRNAs, and CRNAs' permitted scope of practice. In Hospital A, the overall ratio of anesthesiologists to CRNAs may be 1:4, with CRNAs involved in all cases and accorded a broad scope of practice including regional anesthesia, invasive monitoring lines, and other complex procedures. Hospital B in the same city and with similar patients may have a 1:2 ratio, with anesthesiologists handling many cases on their own and CRNAs highly restricted in the types of procedures they may perform. These types of variations are a function of the unique culture and history of each facility, rather than any clinical or empirical rationale.

The following few studies that have examined anesthesia labor efficiencies have two things in common: (1) they indicate a potential for substantial efficiency improvements through increased use of CRNAs, with no diminution of quality or outcomes; and (2) they have not been implemented.

Cromwell and Rosenbach (1990)⁴⁹ studied anesthesiologist productivity and concluded that anesthesiologists are much more productive when delegating tasks to CRNAs than in performing cases alone, and that such delegation "could save society approximately \$500 million in anesthesiologist costs, even allowing for an increase in nurse anesthetists."^{50(p.159)} They also concluded that "the main source of inefficiency stems from paying the anesthesiologist three times what a CRNA earns, even though they perform most tasks equally well."^{51(p.169)}

Kaiser Permanente (1995)⁵² conducted an internal study of operating room best practices in their West Coast operations, including anesthesia labor. They concluded that (1) "The cost of MD direction can be reduced by spreading it over more operating rooms."^{53(p.96)} (2) "A 1:4 ratio is more cost effective than a 1:2 or 1:3 ratio. We found no evidence that the 1:4 ratio is associated with unexpected adverse outcomes."^{54(p.99)} (3) "If CRNAs are credentialed to perform invasive monitoring, fiberoptic bronchoscopy, and intraoperative Transesophageal Echocardiography (TEEE), opportunities [should be] provided CRNAs to utilize these skills."^{55(p.101)} Despite the high degree of control over anesthesia Kaiser could presumably exert as a highly integrated system, the study found tremendous variation in anesthesia staffing—with costs ranging from 62 percent above the "guideline," or recommended level, to 26 percent below. Due in part to anesthesiologist resistance, this study has not yet had a major impact on anesthesia labor allocations within the Kaiser system.

Fassett and Calmes (1995)⁵⁶ reported on a study conducted in 1992 of a 370-bed public teaching hospital to examine how one ACT functions, anesthesiologists' and CRNAs' roles within the ACT, variations in the perceived value of anesthesiologist medical direction, and practice modifications that could lower costs. They found that (1) "Anesthesiologists and nurse anesthetists in this study agreed in their perceptions that more than 70% of these cases did not need medical direction."^{57(p.117)} (2) "Excessive medical direction may be contributing to the higher costs of ACTs. Revision of medical direction guidelines, focusing on patient and operative factors, are recommended to preserve the

ACT as a practice option, while making it more cost effective."⁵⁸(p.117)

Stein (1994)⁵⁹ reported on a trial of alternative levels of medical direction, building on the Fassett and Calmes findings. Patients in a control group were treated using standard facility staffing patterns, primarily one anesthesiologist for two CRNAs following the TEFRA guidelines for anesthesiologist participation. Patients in the study group were prospectively assigned to three groups according to the expected need for medical direction. Group A cases were handled by CRNAs alone. Group B cases were handled by CRNAs following a nominal preoperative consultation with an anesthesiologist, not including patient examination by the anesthesiologist, and no further anesthesiologist involvement. Group C cases were handled on a traditional ACT basis in conformance with TEFRA guidelines. The study found no differences in outcomes between the control and study groups, but significantly lower costs from following the study group guidelines—48 percent lower costs for Group A cases and 36 percent lower costs for Group B.

Except as noted, the findings of these studies into potential improvements in the efficient allocation of anesthesia labor have not been implemented or made the subject of further study in any other hospitals or managed care systems.

Potential for Gains in Efficiency

What division of labor would an efficient market produce between two classes of providers with substantially overlapping capabilities, where one earns approximately three times more than the other? It would use the less costly providers to the greatest possible

What division of labor would an efficient market produce between two classes of providers with substantially overlapping capabilities, where one earns approximately three times more than the other?

extent, and concentrate use of the more costly provider on those cases and roles where the benefits of the higher cost are cost effective and clinically proven. What might this look like as applied to anesthesia care, and how would it affect costs?

Using a hypothetical urban hospital, the following series of tables illustrates the impact on anesthesia labor costs using alternative divisions of labor among anesthesiologists and CRNAs. The analysis could be extended to address additional complexities of staffing requirements and other types of health care staff who may be part of the division of labor under certain circumstances (e.g., registered nurses, anesthesia assistants or technicians, and supervisory staff). However, such features would add considerably to the model's complexity, and their absence should not detract from the model's purpose of illustrating in general terms the potential for savings from efficiency improvements.

Table 1 contains basic assumptions about the hypothetical urban hospital, including the volume of cases requiring anesthesia, the costs and productivity of anesthesia labor, and the anesthesia billing environment. Tables 2 and 3 allocate the case volume at the hospital to three categories that vary according to the need for medical direction, based on the criteria used in the Stein study.⁶⁰ Table 4 shows the

Table 1. Basic assumptions, hypothetical urban community hospital

	Assumptions	Amount	Per
Business volume	Billing volume in cases	10,000	Year
	Billing volume in base/time units	125,000	Year
	Average units per case	12.5	Case
Labor and office costs	Anesthesiologist median salary	\$244,600	Year
	CRNA median salary	\$82,000	Year
	Cost of benefits, overhead taxes	20%	Salary
	Anesthesiologist—total cost of labor	\$293,520	Year
	CRNA—total cost of labor	\$98,400	Year
	Office overhead costs	\$4.00	Unit
Labor productivity	Anesthesiologist/CRNA work days/year	230	Year
	Anesthesiologist/CRNA type A cases/day	3.5	Day
	Anesthesiologist/CRNA type B cases/day	2.5	Day
	Anesthesiologist/CRNA type C cases/day	1.5	Day
Billing environment	Gross charges	\$57.50	Unit
	Avg. discount across all payers	35%	Unit
	Avg. net charges	\$37.38	Unit

number of anesthesiologists and CRNAs required for the three case categories under a variety of staffing options, from anesthesiologist only to CRNA only. Table 5 evaluates the total cost for anesthesia labor across the staffing scenarios from Table 3. Table 6 shows the impact of the staffing scenarios in terms of anesthesiologist and CRNA earnings, and the potential impact on the fee-for-service unit price for anesthesia services.

Basic assumptions

The hospital depicted in Table 1 handles 10,000 cases per year, representing a total of 125,000 billable anesthesia "units" (base + time), or an average of 12.5 units per case. The model assumes anesthesiologist and CRNA earnings are at the median level, an additional 20 percent for benefits and payroll taxes, and \$4 per unit allocated for the over-

head costs of operating the anesthesia professionals' business office. The model assumes equivalent productivity for anesthesiologists and CRNAs based on 230 work days per year, and that the number of cases that can be handled per day decreases as case complexity increases. The billing environment is based on a gross charge level of \$57.50 per unit, an average discount of 35 percent—with commercial payers at 15 to 30 percent, Medicare and Medicaid at over 60 percent, and a modest bad debt allowance—resulting in average net charges of \$37.38 per unit. Any of these assumptions can be altered to more accurately portray the circumstances of a specific hospital, but large changes would be necessary to change the model's basic conclusions as depicted in Tables 5 and 6.

Table 2 provides further detail on the breakdown of surgical case types from less to more complex, based on the previously dis-

Table 2. Case categories according to the need for two anesthesia professionals

Case type	Need for two anesthesia professionals	Factor #1: Patient risk	Factor #2: Patient age	Factor #3: Airway status	Factor #4: Surgical complexity	Factor #5: Vital signs	Factor #6: Time since food/drink	Factor #7: Trauma
A	No need established	ASA score = 1 or 2	12 to 70	Normal	6 or fewer base units	Normal	6+ hours	Would not include trauma
B	Limited prior consultation may be beneficial	ASA score = 3	5 to 80	Variant	7-9 base units	Abnormal but stable	5 or fewer hours	Would include trauma
C	Anesthesia care team may be beneficial	ASA score = 4 or 5	Under 5, over 80	Abnormal	10 or more base units	Abnormal and unstable	5 or fewer hours	Includes all major trauma

cussed approach reported in the Stein and Fassett and Calmes studies. This approach assigns patients to one of three categories based on the expected need for the involvement of two or more anesthesia professionals, including consultation, direction, and two pairs of hands. Category "A" cases are least complex and, according to the study findings, do not require two anesthesia professionals. Indicators for category A cases include the following: overall good health, neither very young nor very old, normal airway status, a relatively simple surgical procedure, normal vital signs, at least six hours since food or drink, and no trauma. At the other extreme, indicators for category C cases include one or more of the following factors: poor patient health, very young or very old, abnormal airway status, a complex surgical procedure, abnormal and unstable vital signs, five or fewer hours since food or drink, and major trauma. Table 3 assigns the 10,000 cases in our hypothetical hospital to category A, B, or C based on the results reported in the Stein study.

Alternative divisions of labor

Table 4 explores alternative divisions of labor for handling the cases in the hypothetical hospital, ranging from anesthesiologist only to CRNA only, and various anesthesia care team models—the full spectrum of possible divisions of labor. For each model, required full-time equivalents (FTEs) are calculated based on the Table 1 case capacity estimates.

Model A depicts a practice based on anesthesiologists exclusively. Models B and C depict a staffing pattern in which there is one anesthesiologist for each CRNA—model B has one anesthesiologist and one CRNA on

Table 3. Allocation of cases

Case type	Need for two anesthesia professionals	Facility case volume (%)	No. of facility cases/year	Avg. total units/case	No. of facility units/year
A	No need established	34%	3,400	8.5	28,890
B	Limited prior consultation may be beneficial	47%	4,700	12.0	56,400
C	Anesthesia care team may be beneficial	19%	1,900	20.9	39,710
	Totals	100%	10,000	12.5	125,000

every case, and model C assumes a 1:2 or 1:3 ratio on simpler cases, with anesthesiologists handling the most complex cases alone. Although models B and C have the same overall staffing ratio, model C requires far fewer total personnel. Models D and E both show an overall division of labor with two CRNAs for each anesthesiologist—model D on a straight 1:2 ratio for all cases, and model E with anesthesiologists performing some cases alone. Model E may be the closest to the average of ACT practice nationally.

The remaining models are more CRNA intensive. Models F and G reflect actual practice at some hospitals and are based on anesthesiologist to CRNA ratios for all cases of 1:3 and 1:4, respectively. Model H depicts a more CRNA-intensive practice, following the need for limited anesthesiologist consultation or assistance in less complex cases indicated in the Stein and Fasset and Calmes studies. Model I depicts a practice based on CRNAs exclusively, a model in use at many rural hospitals and specialty surgery centers for plastic surgery, dental surgery, and eye surgery. These types of surgeries are less likely than inpatient care to be fully covered by insurance and are therefore more price sensitive.

Potential savings

Tables 5 and 6 illustrate the economic impact, and potential for savings, inherent in the alternative divisions of labor. Table 5 shows salary and benefit costs, based on the prevailing earnings levels and benefit costs for anesthesiologists and CRNAs. Compared to model A, the anesthesiologist-only practice, all other models require more total FTEs, but still cost less—except for the model B (straight 1:1 ratio). Models F, G, H, and I, with ratios of 1:3 or greater, cost 67 percent, 59 percent, 46 percent, and 34 percent, respectively, of the anesthesiologist-only model.

Table 6 brings all of the preceding tables together to show the impact on the economics of an anesthesia practice, including (1) annual revenue case type, (2) office overhead costs, (3) CRNA salary and benefits, (4) anesthesiologist salary and benefits, (5) the net profit or loss at prevailing prices, and (6) the percentage price change necessary to break even. A different result is shown for each of the nine divisions of labor depicted in Table 4. A positive percentage in the "net profit or loss" column means that prices would have to be increased to cover overhead costs and main-

Table 4. Division of labor

<i>Model A—Anesthesiologist-only practice</i>						
Case type	CRNA FTEs/case	Anesthesiologist FTEs/case	CRNAs/anesthesiologist	Required CRNAs	Required anesthesiologists	Total required personnel
A	0.00	1.00	0.0	0.0	4.2	4.2
B	0.00	1.00	0.0	0.0	8.2	8.2
C	0.00	1.00	0.0	0.0	5.5	5.5
Totals			0.0	0.0	17.9	17.9
<i>Model B—2.0 Anesthesia professionals for every case</i>						
Case type	CRNA FTEs/case	Anesthesiologist FTEs/case	CRNAs/anesthesiologist	Required CRNAs	Required anesthesiologists	Total required personnel
A	1.00	1.00	1.0	4.2	4.2	8.4
B	1.00	1.00	1.0	8.2	8.2	16.3
C	1.00	1.00	1.0	5.5	5.5	11.0
Totals			1.0	17.9	17.9	35.8
<i>Model C—Avg. 1:1 ratio, some anesthesiologist-only cases</i>						
Case type	CRNA FTEs/case	Anesthesiologist FTEs/case	CRNAs/anesthesiologist	Required CRNAs	Required anesthesiologists	Total required personnel
A	1.00	0.33	3.0	4.2	1.4	5.6
B	1.00	0.50	2.0	8.2	4.1	12.3
C	0.00	1.00	0.0	0.0	5.5	5.5
Totals			1.1	12.4	11.0	23.4
<i>Model D—1.5 Anesthesia professionals for every case</i>						
Case type	CRNA FTEs/case	Anesthesiologist FTEs/case	CRNAs/anesthesiologist	Required CRNAs	Required anesthesiologists	Total required personnel
A	1.00	0.50	2.0	4.2	2.1	6.3
B	1.00	0.50	2.0	8.2	4.1	12.3
C	1.00	0.50	2.0	5.5	2.8	8.3
Totals			2.0	17.9	9.0	26.9
<i>Model E—Avg. 1:2 ratio, some anesthesiologist-only cases</i>						
Case type	CRNA FTEs/case	Anesthesiologist FTEs/case	CRNAs/anesthesiologist	Required CRNAs	Required anesthesiologists	Total required personnel
A	1.00	0.25	4.0	4.2	1.1	5.3
B	1.00	0.25	4.0	8.2	2.0	10.2
C	0.80	1.00	0.8	4.4	5.5	9.9
Totals			2.0	16.8	8.6	25.4

(continues)

Table 4. continued

<i>Model F—1.33 Anesthesia professionals for every case</i>						
Case type	CRNA FTEs/case	Anesthesiologist FTEs/case	CRNAs/anesthesiologist	Required CRNAs	Required anesthesiologists	Total required personnel
A	1.00	0.33	3.0	4.2	1.4	5.6
B	1.00	0.33	3.0	8.2	2.7	10.9
C	1.00	0.33	3.0	5.5	1.8	7.3
Totals			3.0	17.9	5.9	23.8

<i>Model G—1.25 Anesthesia professionals for every case</i>						
Case type	CRNA FTEs/case	Anesthesiologist FTEs/case	CRNAs/anesthesiologist	Required CRNAs	Required anesthesiologists	Total required personnel
A	1.00	0.25	4.0	4.2	1.1	5.3
B	1.00	0.25	4.0	8.2	2.0	10.2
C	1.00	0.25	4.0	5.5	1.4	6.9
Totals			4.0	17.9	4.5	22.4

<i>Model H—CRNA-intensive care team, based on California study findings</i>						
Case type	CRNA FTEs/case	Anesthesiologist FTEs/case	CRNAs/anesthesiologist	Required CRNAs	Required anesthesiologists	Total required personnel
A	1.00	0.00	—	4.2	0.0	4.2
B	1.00	0.10	10.0	8.2	0.8	9.0
C	1.00	0.25	4.0	5.5	1.4	6.9
Totals			8.2	17.9	2.2	20.1

<i>Model I—CRNA-only practice</i>						
Case type	CRNA FTEs/case	Anesthesiologist FTEs/case	CRNAs/anesthesiologist	Required CRNAs	Required anesthesiologists	Total required personnel
A	1.00	0.00	—	4.2	0.0	4.2
B	1.00	0.00	—	8.2	0.0	8.2
C	1.00	0.00	—	5.5	0.0	5.5
Totals			—	17.9	0.0	17.9

tain prevailing CRNA and anesthesiologist salary levels. A negative percentage means that prices could be decreased without falling below prevailing salary levels.

In the marketplace, of course, anesthesiologists and CRNAs are not free to charge any price they wish in order to "hold earning levels constant." A price increase may not be accepted

Table 5. Salary costs associated with alternative divisions of labor

Model	Required professionals			Personnel costs (in \$ millions)			Total as % of Model A
	CRNAs	Anesthesiologists	Total	CRNAs	Anesthesiologists	Total	
Model A—Anesthesiologist-only practice	0.0	17.9	17.9	\$0.00	\$5.26	\$5.26	100%
Model B—2.0 anesthesia professionals for every case	17.9	17.9	35.8	\$1.76	\$5.26	\$7.02	134%
Model C—Avg. 1:1 ratio, some anesthesiologist-only cases	12.4	11.0	23.4	\$1.22	\$3.23	\$4.45	85%
Model D—1.5 anesthesia professionals for every case	17.9	9.0	26.9	\$1.76	\$2.63	\$4.39	84%
Model E—Avg. 1:2 ratio, some anesthesiologist-only cases	16.8	8.6	25.4	\$1.65	\$2.53	\$4.18	80%
Model F—1.33 anesthesia professionals for every case	17.9	5.9	23.8	\$1.76	\$1.73	\$3.50	67%
Model G—1.25 anesthesia professionals for every case	17.9	4.5	22.4	\$1.76	\$1.31	\$3.08	59%
Model H—CRNA-intensive care team, based on California study findings	17.9	2.2	20.1	\$1.76	\$0.64	\$2.41	46%
Model I—CRNA-only practice	17.9	0.0	17.9	\$1.76	\$0.00	\$1.76	34%

by health care purchasers, in which case anesthesia professionals would need to reduce earnings or overhead costs to break even. On the other hand, a potential price decrease does not automatically mean that a health plan will receive the full decrease. This will only occur if the market is sufficiently competitive, and the health plan understands the internal economics of anesthesia sufficiently to negotiate a contract that passes along all or most of the savings. To

the extent this does not occur, the owners of the anesthesia practice will be able to retain higher earnings.

In each model, the annual revenue and office overhead costs are the same, giving our hypothetical practice approximately \$4.2 million to meet the costs of anesthesia professional labor. In model E, the practice setting that may be closest to "typical" for urban community hospitals, no price change

Table 6. Impact on practice economics from alternative divisions of labor

<i>Model A—Anesthesiologist-only practice</i>						
Case type	Annual revenue by case type	Office overhead costs	CRNA salary and benefits	Anesthesiologist salary and benefits	Profit or loss	Price change need to break even
A	\$1,079,756	\$115,559	\$0	\$1,239,712	(\$275,515)	26%
B	\$2,107,950	\$225,600	\$0	\$2,399,207	(\$516,857)	25%
C	\$1,484,161	\$158,840	\$0	\$1,616,487	(\$291,166)	20%
Totals	\$4,671,868	\$499,999	\$0	\$5,255,406	(\$1,083,537)	23%
<i>Model B—2.0 Anesthesia professionals for every case</i>						
Case type	Annual revenue by case type	Office overhead costs	CRNA salary and benefits	Anesthesiologist salary and benefits	Profit or loss	Price change need to break even
A	\$1,079,756	\$115,559	\$415,602	\$1,239,712	(\$691,117)	64%
B	\$2,107,950	\$225,600	\$804,313	\$2,399,207	(\$1,321,170)	63%
C	\$1,484,161	\$158,840	\$541,913	\$1,616,487	(\$833,079)	56%
Totals	\$4,671,868	\$499,999	\$1,761,829	\$5,255,406	(\$2,845,366)	61%
<i>Model C—Avg. 1:1 ratio, some anesthesiologist-only cases</i>						
Case type	Annual revenue by case type	Office overhead costs	CRNA salary and benefits	Anesthesiologist salary and benefits	Profit or loss	Price change need to break even
A	\$1,079,756	\$115,559	\$415,602	\$409,105	\$139,490	-13%
B	\$2,107,950	\$225,600	\$804,313	\$1,199,603	(\$121,567)	6%
C	\$1,484,161	\$158,840	\$0	\$1,616,487	(\$291,166)	20%
Totals	\$4,671,868	\$499,999	\$1,219,916	\$3,225,195	(\$273,243)	6%
<i>Model D—1.5 Anesthesia professionals for every case</i>						
Case type	Annual revenue by case type	Office overhead costs	CRNA salary and benefits	Anesthesiologist salary and benefits	Profit or loss	Price change need to break even
A	\$1,079,756	\$115,559	\$415,602	\$619,856	(\$71,261)	7%
B	\$2,107,950	\$225,600	\$804,313	\$1,199,603	(\$121,567)	6%
C	\$1,484,161	\$158,840	\$541,913	\$808,243	(\$24,835)	2%
Totals	\$4,671,868	\$499,999	\$1,761,829	\$2,627,703	(\$217,663)	5%
<i>Model E—Avg. 1:2 ratio, some anesthesiologist-only cases</i>						
Case type	Annual revenue by case type	Office overhead costs	CRNA salary and benefits	Anesthesiologist salary and benefits	Profit or loss	Price change need to break even
A	\$1,079,756	\$115,559	\$415,602	\$309,928	\$238,667	-22%
B	\$2,107,950	\$225,600	\$804,313	\$599,802	\$478,235	-23%
C	\$1,484,161	\$158,840	\$433,530	\$1,616,487	(\$724,696)	49%
Totals	\$4,671,868	\$499,999	\$1,653,446	\$2,526,217	(\$7,794)	0%

Table 6. continued

<i>Model F—1.33 Anesthesia professionals for every case</i>						
Case type	Annual revenue by case type	Office overhead costs	CRNA salary and benefits	Anesthesiologist salary and benefits	Profit or loss	Price change need to break even
A	\$1,079,756	\$115,559	\$415,602	\$409,105	\$139,490	-13%
B	\$2,107,950	\$225,600	\$804,313	\$791,738	\$286,299	-14%
C	\$1,484,161	\$158,840	\$541,913	\$533,441	\$249,968	-17%
Totals	\$4,671,868	\$499,999	\$1,761,829	\$1,734,284	\$675,756	-14%

<i>Model G—1.25 Anesthesia professionals for every case</i>						
Case type	Annual revenue by case type	Office overhead costs	CRNA salary and benefits	Anesthesiologist salary and benefits	Profit or loss	Price change need to break even
A	\$1,079,756	\$115,559	\$415,602	\$309,928	\$238,667	-22%
B	\$2,107,950	\$225,600	\$804,313	\$599,802	\$478,235	-23%
C	\$1,484,161	\$158,840	\$541,913	\$404,122	\$379,286	-26%
Totals	\$4,671,868	\$499,999	\$1,761,829	\$1,313,851	\$1,096,188	-23%

<i>Model H—CRNA-intensive care team, based on California study findings</i>						
Case type	Annual revenue by case type	Office overhead costs	CRNA salary and benefits	Anesthesiologist salary and benefits	Profit or loss	Price change need to break even
A	\$1,079,756	\$115,559	\$415,602	\$0	\$548,595	-51%
B	\$2,107,950	\$225,600	\$804,313	\$239,921	\$838,116	-40%
C	\$1,484,161	\$158,840	\$541,913	\$404,122	\$379,286	-26%
Totals	\$4,671,868	\$499,999	\$1,761,829	\$644,042	\$1,765,997	-38%

<i>Model I—CRNA-only practice</i>						
Case type	Annual revenue by case type	Office overhead costs	CRNA salary and benefits	Anesthesiologist salary and benefits	Profit or loss	Price change need to break even
A	\$1,079,756	\$115,559	\$415,602	\$0	\$548,595	-51%
B	\$2,107,950	\$225,600	\$804,313	\$0	\$1,078,037	-51%
C	\$1,484,161	\$158,840	\$541,913	\$0	\$783,408	-53%
Totals	\$4,671,868	\$499,999	\$1,761,829	\$0	\$2,410,040	-52%

is needed for the practice to break even. The practice earns a profit on the simpler cases (types A and B) handled on a 1:4 basis, which is offset by a loss on the more complex cases handled as 1:1 or anesthesiologist only.

In models A, B, C, and D, a price increase

would be necessary to break even. For model D, where all cases are handled on a 1:2 basis, a modest five percent increase would suffice to maintain earnings at the median levels, and model C requires only a six percent increase. Model A, the anesthesiologist-only practice,

would require a substantial and probably untenable 23 percent price increase to maintain earning levels. Model B, with two professionals for every case, clearly cannot work since it requires a 61 percent increase.

Models F, G, H, and I allow room for a price decrease or to maintain current prices and return higher earnings to the practice owners. For model F, where all cases are handled on a 1:3 basis, prices could be decreased 14 percent. Model G, with straight 1:4 ratios as recommended by the Kaiser study, allows for a 23 percent decrease. Model H, based on the Stein and Fassett and Calmes studies, yields a 38 percent decrease. And if a CRNA-only practice were feasible in our hypothetical hospital, as depicted in model I, prices could be reduced by more than one-half (52 percent) without going below the median earning levels.

Anesthesia services account for an estimated 2.4 percent of total health care costs for commercial group health insurance. If model E is closest to today's norm and the basis for that 2.4 percent, what would it mean to a health care purchaser to move to model F, G, H, or I? If an employer's average health care costs per employee per year are \$3,500,⁶¹ 2.4 percent represents \$84 per employee. Moving to model F would save \$12 per employee or 0.3 percent of total health care costs, model G saves \$19 per employee or 0.5 percent, model H saves \$32 or 0.9 percent, and model I saves \$44 or 1.2 percent. For an employer with 100 employees, model H (for example) would mean a \$3,200 annual health insurance savings, or almost 1 percent. A large employer with 100,000 employees, such as a *Fortune 500* company or large government agency, would save \$3.2 million annually.

The Challenge to Managed Care

The goal of managed care organizations with respect to anesthesia services should be to provide high quality care as efficiently as possible. Unique features of the market for anesthesia labor have prevented managed care from reshaping anesthesia practice. The challenge to managed care is to overcome these barriers and to create an anesthesia practice structure with incentives and opportunities for both providers to work together, to pool their energies and creativity toward a common end.

Some health plans have begun some modest restructuring of anesthesia incentives, such as contracting for anesthesia services on a capitation basis. While this may be a step in the right direction, it does not necessarily change incentives appropriately or enough. If capitation is limited to anesthesiologist costs, it does not capture the full anesthesia "production function" including CRNAs and, ideally, incentives for efficient use of anesthetic agents, drugs, and supplies. If the capitation amount is based strictly on what has been paid in the past, perhaps modestly discounted, it tends to lock in historical inefficiencies rather than promote new and more efficient models. And if capitation includes anesthesiologists and CRNAs, but anesthesiologists are able to "call the shots" in terms of the division of labor because they are the sole business owners and decision makers, they will still manage the business to maximize anesthesiologist earnings and job security, not anesthesia labor efficiency.

What might a new anesthesia practice model look like? First, it should contain incentives for anesthesia providers to (1) use supplies, drugs, and equipment efficiently; (2)

recognize the impacts of anesthesia practice methods in terms of patient recovery time, patient satisfaction, and other "beyond the operating room" factors; and (3) improve the coordination and teamwork of anesthesia with other operating room and hospital functions.

Next, a new anesthesia practice model should contain incentives for good outcomes, high quality, and a high degree of teamwork and collegiality among anesthesia professionals. If anesthesiologists and CRNAs do not see each other as partners with a shared incentive to improve the practice, whether as employees or as owners together, they may instead see each other primarily as competitors engaged in a "zero sum game." While recognizing anesthesiologists' and CRNAs' distinct skills and capabilities, a new practice model should allow both to participate equally in the benefits, risks, and management of the anesthesia practice, to the extent that they wish to do so.

Finally, a new anesthesia practice model must contain incentives for the efficient use

of labor. To the extent that this may result in decreased demand for one type of provider and increased demand for another, methods should be developed to allow adjustments to be made as fairly and gradually as possible, while maintaining progress toward the efficiency goals.

• • •

The incentive for managed care to make progress toward a new and better anesthesia practice model is money. Whichever health plan "figures it out" first in its market area could gain a price advantage over its competitors of as much as a full percentage point—enough to tip the balance in some marketing situations. Achieving that percentage point will be difficult, and require a much greater level of attention and sophistication than managed care has shown for anesthesia in the past. But then, most of the "easy" savings, such as reducing inpatient lengths of stay, have already been taken.

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Education News

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Health educational costs, provider mix, and healthcare reform: A case in point—nurse anesthetists and anesthesiologists

Key words: Educational costs (nurse anesthetists/anesthesiologists), healthcare reform, health provider mix, health workforce.

The appropriate human resources needed for providing anesthesia care in this country have been under debate for at least 50 years. Nurse anesthetists have been the major, hands-on providers of anesthesia services since the late 1870s. According to Rosemary Stevens, during the midst of World War II (1942), there were 17 nurse anesthetists for every one physician anesthesia provider.¹

With the end of the war, and the formalization of the medical specialty in anesthesiology, more medical residencies were established. The American Society of Anesthesiologists (ASA) was not long in stating that its goal was the establishment of an all-physician specialty, i.e., eliminating and phasing out America's nurse anesthetists.² This goal has never been achieved, and the attempt to replace nurse anesthetists limited the vision of medical anesthesiology's leaders in defining what a truly medical role in this specialty should be, then and for the future. Consequently, the medical specialty that developed was patterned after the nursing specialty, thus creating the great functional overlap between medicine and nursing, rather than capitalizing on the unique background of medicine to make that specialty the true internist of surgical care or the expert in critical care and resuscitative medicine.

The resulting conflict concerning the appropriate provider mix in the field of anesthesiology has been long debated, though the number of physicians within this field has seriously limited ASA's ability to achieve its primary goal of replacing nurses in the specialty.

Can prepare 10 CRNAs for the cost of one anesthesiologist

As a part of its data collection in support of

nurse anesthesia, the Texas Association of Nurse Anesthetists (TANA) undertook a study to assess the differential costs of preparing nurse anesthetists and anesthesiologists. Based on data gathered reflecting 1990 and 1991 costs from the Texas Higher Education Coordinating Board^{3,4} and from the Health Care Finance Administration of the U.S. Department of Health and Human Services,⁵ it cost approximately \$635,000 to prepare one anesthesiologist from undergraduate studies through medical school and postgraduate medical education. The average cost of preparing a CRNA in Texas for approximately the same period was \$59,000, with a low-end cost of \$49,700 and a high-end cost of \$75,000 including both undergraduate and graduate educational programs.³ (See Table I and notes.)

Corroboration of medical education costs was sought from the American Medical Association (AMA), the American Association of Medical Schools, and the Liaison Committee on Medical Education. None of the organizations had such data and replied that such data were hard to come by.

Based on the aforementioned costs, 10 CRNAs could be prepared for the cost of preparing one anesthesiologist. In addition, those 10 CRNAs could have entered the work force and collectively provided a total of 35 to 40 years of service as professional nurses or nurse anesthetists by the time the one anesthesiology resident was ready to enter practice.

Provider mix

Both CRNAs and anesthesiologists are appropriate providers for anesthesia care. Outcome studies of care show that in the broad area of overlap between medicine and nursing which includes the majority of the components of anesthesia services, both providers afford the same high quality of services.⁶ Both providers tend to utilize medical consultation for those patients having significant medical problems or complications. As a result of

Table I**Data concerning cost of preparing nurse anesthetists and anesthesiologists in Texas**

Practitioner	BS/BSN degree 36-42 months	Clinical practice as RN ¹	Graduate education 24-30 months ²	Medical education 36 months	Postgraduate education 48 months ³	Total
CRNA ⁴						
high	\$31,758	2-4 yrs	\$42,419	---	----	\$ 75,177
average	\$26,203	on	\$32,950	---	----	\$ 59,153
low	\$ ----	average	\$23,499	---	----	\$ 49,702
Anesthesiologist	Undergraduate			Medical school	Residency	
high						
average	\$20,000 ⁵			\$276,000 ⁶	\$339,348 ⁷	\$635,348 ⁸
low						

1. After graduating from nursing school and attaining licensure, a nurse must work in an acute or critical care nursing setting at least 1 year before applying for entrance into a nurse anesthesia program. Most students enter the graduate nurse anesthesia educational program with 2-4 years of nursing experience. As a result, in the time it takes to prepare an anesthesiologist, a CRNA has practiced nursing and/or nurse anesthesia 3½-4 years.

2. Most nurse anesthesia graduate programs are 24-30 months in length. Some of the cost variance may result from those differences, in addition to those cited in the Texas Higher Education Coordinating Board Report. Upon completion of the program, a graduate is eligible to write the certification examination in the specialty. In Texas, graduates may work without certification, but information from the American Association of Nurse Anesthetists demonstrates that only 6 of some 1,700 CRNAs in the state do not have initial certification, and 25 are not recertified (who are eligible for recertification).

3. Upon graduation from medical school, physicians enter a 4-year anesthesiology residency program: 1 year is dedicated to internal medicine, 2 years to general anesthesiology, and 1 year is spent as a fellow in a subspecialty area or in further basic science education and research. After completion of the fourth year, the graduate is eligible for certification.

4. These figures for the cost of preparing CRNAs in the state of Texas come from the Texas Nursing Education Cost Study and Funding Recommendations, A Report to the Legislative Budget Board in Response to: 71st Legislature, Senate Bill 2222, Article III, rider 25, Regular Session 1989, October 1990.

5. This figure represents a low estimate of the educational costs of obtaining a baccalaureate degree with a pre-medicine major.

6. This figure is based on information from the Texas Higher Education Coordinating Board, printed in the Report of the Texas Health Policy Task Force Report, released in October 1992. The figure quoted was "nearly \$69,000" per medical student per year, "with in-state student tuition of \$5,463 annually and out-of-state student tuition \$21,852 annually."

7. This figure (\$84,837 per resident per year) has been obtained from the director of Hospital Payment Policy, HCFA, in a letter dated July 27, 1992 to Kathleen A. Michels, RN, JD, director of Federal Government Affairs, American Association of Nurse Anesthetists. These figures are for fiscal year 1990, and include data from 1,201 teaching hospitals. This figure is higher, as would be expected than that found reported in the *Journal of Academic Medicine*, 1989;64(6):314-319, for hospital costs in the St. Paul/Minneapolis area in 1983-1984. This study reported that cost to be \$73,000. Most residents are paid a stipend of from \$24,000 to \$32,000 per year. While residents generate revenue from the supervised services performed, that revenue generally goes to the medical school physician practice plan as a supplement to physician salaries paid by the state if associated with a state medical school.

8. Considering the average cost of preparing nurse anesthetists, it becomes apparent that about 10 nurse anesthetists can be prepared for the cost of preparing 1 anesthesiologist. Further, cumulatively nurse anesthetists will have provided at least 35-40 years of nursing and nurse anesthesia services to the community, either as professional nurses or nurse anesthetists, by the time the anesthesiology resident graduates.

Note 1. While this chart reflects the data found concerning the cost of preparing nurse anesthetists and anesthesiologists in Texas, it is probably reasonably accurate for preparing nurse midwives and obstetrician/gynecologists. The cost of preparing nurse practitioners is somewhat less on the average by about \$4,000. The cost of residency education for a primary care physician (internal medicine or family practice) will be \$84,847 less than that of preparing an anesthesiologist, or \$254,511, since the primary care physician has a 3-year rather than a 4-year residency.

Note 2. It should be noted that physicians in the state of Texas who qualify as state residents seldom pay more than 10-15% of the actual cost of their education, while the rest is borne by society. On the average, nurses pay a significantly greater percentage of their educational costs than do physicians.

current patterns of practice (based more on reimbursement patterns than on valid patient care criteria), a variety of provider mix ratios have been suggested. Two federally mandated studies concerning nurse anesthetists and other publications resulting from them have advocated a provider mix of one anesthesiologist to 2 to 3 CRNAs as a basis of affording cost-effective anesthesia to the American public.^{7,8} While the majority of CRNAs in this country work with anesthesiologists, about 20% to 25% of the American public is served solely by CRNAs. Many of these CRNAs reside in rural areas. Anesthesiologists have not found rural America sufficiently fiscally rewarding to move into these areas in significant numbers.

The American Association of Nurse Anesthetists (AANA) has historically contended that fixed ratios as a measure of personnel mix for the nation's health facilities are inappropriate. Fixed ratios fail to take into consideration the population served or the facility's type of workload. Further, CRNAs working alone historically have provided and continue to provide high-quality, essential services which would not otherwise have been available, affording many people healthcare in their own communities.

Rosenbach and Cromwell found that when CRNAs and anesthesiologists work together, each provider was equally likely to be assigned the most complex of cases. They also found that when CRNAs worked alone, the complexity of anesthesia services required was somewhat lower than when CRNAs and anesthesiologists worked together; however, CRNAs working alone did more emergency anesthesia cases on a percentage basis than did anesthesiologists working alone or anesthesiologists and CRNAs working together. The decrease in complexity observed by Rosenbach and Cromwell when CRNAs worked alone reflected only 6% of the surgical procedures for which anesthesia is usually provided.⁹

The ASA has advocated medical direction of all nonphysician anesthetists, generally at a 1:2 anesthesiologist:CRNA ratio. And, in the development of Medicare reimbursement regulations for CRNAs and anesthesiologists, ASA supported this recommendation, often citing quality as the basis for that decision. However, based on the lobbying by the AANA and its members and support from many anesthesiologists who work with CRNAs, a 4:1 CRNA:anesthesiologist ratio was established as the maximum number of concurrent cases for which an anesthesiologist could gain reimbursement for medical direction of CRNAs. Attempts by ASA to use such ratios for qualitative purposes or as a standard of care were disavowed by the Health

Care Financing Administration (HCFA), which stated the ratio served no other purpose than to define the requirements for reimbursement of anesthesiologists who practiced in a medical direction mode of practice.¹⁰

The effectiveness of CRNAs working alone or working without medical direction or supervision has long been established in rural settings and in many community hospitals, even when CRNAs are competing with anesthesiologists for cases. However, most anesthesiologists continue to espouse medical and/or anesthesiologist supervision of CRNAs for administration of all anesthetics. While many such proponents put a quality spin on their arguments, economics and ego are often the hidden motivations, whether conscious or not.

Fassett and Calmes, in a study performed in 1992 and reported in 1995, found that in an urban community hospital there was general consensus among anesthesiologists and CRNAs that only about *one-fourth* of the anesthetics given required either medical direction or a second pair of educated hands, and when this finding was operationalized, the cost of anesthesia services could be reduced within that facility.^{11,12} This number probably will vary somewhat among facilities based on the providers from whom consensus on this issue is sought, on the population actually served, and the characteristics of the workload of a facility. However, the workload depicted in Fassett and Calmes' study is reasonably characteristic of many suburban community hospitals.

The Fassett and Calmes' study tends to support the views of some CRNA leaders who, in projecting anesthesia personnel needs nationwide, believe that preparing one anesthesiologist for every 4 to 6 CRNAs prepared could achieve an anesthesia provider mix that would not compromise the quality of anesthesia services but would at the same time achieve maximum cost-effectiveness. However, greater involvement of anesthesiologists in anesthesia-related services, such as consulting for and participating in the preparation of critically ill patients for anesthesia, management of acute and chronic pain, and affording intensivist services to critically ill or injured patients before, during, and following anesthesia and surgical intervention, the educational preparation ratio might more appropriately be one anesthesiologist to 3 to 4 CRNAs.

Long-term costs of preparing nurses versus physicians

In 1992 in the State of Texas, we were graduating 88 to 95 anesthesiologists and about 40 CRNAs annually, a situation totally antithetical to cost containment and improved access to care.^{7,8,11} Further,

when considering cost of preparation of both providers solely for their anesthesiology training (based on figures in Table I), it was costing \$30.0 to \$32.3 million to prepare anesthesiologists annually, while only \$2.64 million was spent to prepare CRNAs.

If the numbers of each provider prepared had been reversed (i.e., graduating 88-95 CRNAs and 40 anesthesiologists annually), about 50% or \$15 million could have been saved in training costs annually. When comparing total educational costs, an output of 95 anesthesiologists a year represented an investment of \$60.3 million, as compared to an output of 40 CRNAs representing an investment of \$2.36 million. Again, if these figures had been reversed and 95 CRNAs and 40 anesthesiologists had been prepared annually, the total annual educational investment would have been reduced by approximately \$30 million.

During the 1980s, a large number of nurse anesthesia programs within academic health centers were terminated to utilize the educational space to increase the number of anesthesiology residency slots. It was also relatively common to hear anesthesiologists who were physician residency program directors express the notion that it was cheaper to train residents than employ CRNAs in teaching hospitals. This was not true. In 1990, the cost of preparation of residents was \$84,837 per resident per year.⁵ The average income of CRNAs for 1990, as reported by the AANA, was \$76,000; the net median earning before taxes for anesthesiologists as reported by the AMA for the same year was \$207,400. Further, in this type of situation, comparing the cost of employing CRNAs and the cost of training residents was answering the wrong question. The questions should have been, what was the differential cost of preparing a nurse versus a physician as an anesthesia provider, and what would be the impact of such preparation on long-term costs of anesthesia care?

Rosenbach and Cromwell reported that the Kaiser Permanente Hospitals they studied had a ratio of nurse anesthetists to anesthesiologists which ranged from 1:1 to 4:1, and that the provider mix did not seem to be a function of the case mix, since the tertiary care facility had a 3:1 ratio. They also reported that in 1986 there were 1.2 CRNAs for every one anesthesiologist. They projected that with the increasing number of graduates of anesthesiology residencies and the decreased number of nurse anesthesia graduates, that ratio would be 1:1 by 1996 and society would be in danger of losing its chance for a more cost-effective anesthesia service.¹²

J. G. Reves, MD, director, Duke Heart Center,

Durham, North Carolina, in a presentation on the anesthesia work force at the AANA Assembly of States meeting, St. Louis, November 1995, reported that the current ratio of nurse anesthetists to anesthesiologists was 1:1.2, a reverse of the 1986 ratio and considerably ahead of Cromwell and Rosenbach's projections.¹³

The considerable increase in the number of anesthesiologists prepared has been reflected in significantly higher costs for anesthesia services, particularly within the private insurance sector. Further, the current estimate is that under a managed care delivery system, there are approximately 13,000 too many anesthesiologists.¹⁴ In training costs (1990 to 1991 dollars), we have expended something more than \$8.25 billion for this overage. Had all 13,000 of those physicians who trained as anesthesiologists been trained as primary care physicians where a shortage continues to persist, we could have still saved \$1.1 billion.

Joseph Califano, President Lyndon Johnson's Secretary of the Department of Health, Education, and Welfare, during the period of Medicare enactment and implementation, wrote:

"Anticipating sharply increased demand for health-care services, we pushed through Congress laws to train more doctors and nurses, build more hospitals, and set up community health centers. The assumption was that we were playing by traditional economic rules: the more doctors and hospitals, the more competition, the more efficient and less costly the services."

By 1967 and 1968 we realized how misguided this assumption was. The rise of healthcare costs was accelerating dramatically."¹⁵

Uwe Rheinhardt, a healthcare economist who studied the Medicare program at the time of its enactment as the basis for his doctoral dissertation, disagreed with the common wisdom of the time that a physician shortage existed. From his research, he concluded that if physicians utilized support personnel more efficiently, there would be adequate numbers of physicians to meet the health needs of the nation.¹⁶ No one listened, and federal and state governments put up the money to significantly increase the number of medical schools and double the output of physicians prepared, which to this day, goes unabated, though efforts are being expended to trim residency training and shift more resources to preparation of primary care providers. Unfortunately, the Texas logic to meet the greater needs for primary care physicians was to simply add 20 more spaces to each medical school class and obtain agreement from newly admitted students to fill the primary care residencies, rather than imposing such requirements on existing students, a move medical school deans opposed.

Conclusions

Today, most health analysts agree that we have too many physicians, particularly specialists. There are estimates that the overage of medical specialists will reach 160,000 by the year 2000. If this is accurate, in 1992 dollars, we have expended slightly more than \$101 billion educating that overage. Further, in changing from a private, fee-for-service delivery system to a capitated managed care system, that excess of specialists may become even greater.

The cost data in the TANA study indicate a need for a change in state and federal policy with regard to the funding of health professional education, particularly as relates to CRNAs, nurse midwives, and nurse practitioners who serve as cost-effective alternative providers for physicians in the delivery of health services wherein the legal scopes of practice of these providers overlap. These cost data, along with the myriad of research demonstrating the high quality of services provided by many nonphysician providers, indicate that the health provider mix can be a critical factor in containing costs in healthcare. Fewer physicians and more advanced practice nurses and other nonphysician providers would lead to more disease prevention and health maintenance services and less procedural medicine. The overuse of procedural medicine has often been cited as one of the causes of ever-increasing healthcare costs.

Unfortunately, no study to date in the United States had determined the actual numbers of health providers we need, including the appropriateness of the provider mix, to truly operate and maintain a cost-effective health delivery system. Of greater concern is the fact that no such study can be accurately made without a national policy addressing our commitment to a defined level of health services that should be universally available to the American public, a political issue with which this nation has had difficulty coming to grip.

Neither can the nation rely on health professionals alone to determine and achieve a cost-effective workforce, for a variety of reasons, two of which stand out: (1) professional self-interest when governmental or other money is available for education, and (2) the potential liability under the anti-trust laws for attempting to control the workforce to promote professional self-interest. However, in the 1980s had anesthesiology departments not closed or reduced in size their nurse anesthesia educational programs, transferring those spaces to anesthesiology residency training, we would not have had the degree of overage of anesthesiologists being reported today, and Medicare's graduate medical education costs might have been somewhat less.

It is imperative that a national study be commissioned to determine an appropriate provider mix in the health workforce. Until such data can be a part of our healthcare planning and implementation, a cost-effective healthcare system will remain a dream, and healthcare reform will continue to haunt federal and state legislative agendas ad infinitum.

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SURGICAL MORTALITY AND TYPE OF ANESTHESIA PROVIDER

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Although estimates of anesthesia-related deaths today are as low as 1 in 200,000 to 300,000 cases, questions remain about surgical patients' safety related to types of anesthesia providers. We studied the effect of type of anesthesia provider on mortality rates of Medicare patients undergoing 8 different surgical procedures.

Risk-adjusted mortality rates were analyzed for 404,194 inpatients undergoing surgery and having complete, unambiguous Medicare bills for anesthesia. Mortality was compared for anesthesiologists working alone, Certified Registered Nurse Anesthetists (CRNAs) working alone, and anesthesia care teams. Procedure-specific risk-

adjustment models were derived using stepwise logistic regression. Predictions were adjusted for institutional and geographic factors.

Mortality rates for conditions studied ranged from 0.11% to 1.20%. Observed and predicted values by type of provider were not statistically significantly different. Hospitals without anesthesiologists had results similar to hospitals where anesthesiologists provided or directed anesthesia care.

Key words: Anesthesia mortality, anesthesia providers, nurse anesthetist, quality of care, surgical mortality.

Success in reducing anesthesia-related mortality has been exemplary, with current estimates of death rates as low as 1 death per 200,000 to 300,000 cases.¹ Despite this commendable record, questions remain about surgical patient safety related to types of anesthesia providers.

On January 18, 2001, the Health Care Financing Administration (now the Centers for Medicare & Medicaid Services) published a rule² allowing states and individual hospitals to decide whether physicians must supervise anesthesia administration by Certified Registered Nurse Anesthetists (CRNAs) in order for hospitals to receive Medicare reimbursement. Before this rule could take effect, a new administration invoked "safety issues" as a rationale for replacing it with a rule that mandates physician supervision unless a state governor obtains a waiver, after consultation with the state's boards of medicine and nursing.³ Currently, 6 states have obtained such waivers. In states considering these waivers, state governors have become immersed in sometimes fierce and expensive political controversies as anesthesiologists pressed for mandatory supervision and CRNAs stoutly defended their professional competence. Without recent valid scientific data, governors must contend with contradictory interpretations of outdated or seriously flawed research studies.⁴⁻⁷ Furthermore, in states that grant waivers, hospitals and surgeons must decide how the composition of an operative team will affect surgical outcomes.

We studied the effect of type of anesthesia provider

on surgical mortality associated with selected surgical procedures performed on Medicare beneficiaries.

Methods

Part A (ie, hospital claims) and Part B (ie, professional claims) Medicare data were analyzed for patients hospitalized in 1995, 1996, or 1997 in 1 of 22 states if they underwent 1 of the following operations: (1) carotid endarterectomy, (2) cholecystectomy, (3) herniorrhaphy, (4) hysterectomy, (5) knee replacement, (6) laminectomy, (7) mastectomy, or (8) prostatectomy. Patients also had to (1) reside in the state where the operation was performed, (2) undergo the procedure within 2 days after admission, and (3) have a principal diagnosis that could be treated appropriately by the procedure performed. Table 1 lists qualifying *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* procedure codes and associated ICD-9-CM principal diagnostic codes. States were selected to yield a reasonable representation of CRNAs practicing in urban and rural facilities across the United States. A total of 586,422 cases met initial inclusion criteria.

The type of anesthesia provider (ie, an anesthesiologist alone, a CRNA alone, or a team of an anesthesiologist and a CRNA) was obtained from part B Medicare billing data. Cases were eliminated from development of risk-adjustment models if they lacked part B data, had invalid provider codes, were coded as emergencies, or came from any hospital that performed fewer than 15 similar operations on Medicare beneficiaries during the 3-year study period. Table 2 shows the number of cases eliminated by each criterion.

Table 1. Qualifying *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* procedure codes and associated ICD-9-CM principal diagnosis codes

Surgical procedure	ICD-9-CM codes*
Carotid endarterectomy	Procedure code: 38.12 Principal diagnosis codes: 433.10, 433.30, 435.8x, 435.9x
Cholecystectomy	Procedure code: 51.2x Principal diagnosis codes: 574.xx, 575.0x, 575.1x, 575.2x
Herniorrhaphy (uncomplicated)	Procedure code: 53.xx Principal diagnosis codes: 550.9x, 553.xx
Hysterectomy for benign disease	Procedure codes: 68.3x, 68.4x, 68.5x, 68.6x, 68.7x, 68.8x, 68.9x Principal diagnosis codes: 218.xx, 219.xx, 220.xx, 233.1x, 233.2x, 256.xx, 614.xx, 615.xx, 617.xx, 618.xx, 619.xx, 616.0x, 620.xx, 621.xx, 622.xx, 626.xx, 627.xx, 625.2x, 625.3x, 625.4x, 625.5x, 625.6x
Knee replacement	Procedure codes: 81.54, 81.55 Principal diagnosis codes: 696.0x, 714.xx, 717.xx, 715.x6, 716.x6, 718.x6, 719.x6
Laminectomy	Procedure code: 80.5x Principal diagnosis codes: 721.xx, 722.xx, 723.0x, 724.0x
Mastectomy	Procedure codes: 85.22, 85.23, 85.3x, 85.4x Principal diagnosis codes: 174.xx, 217.xx, 233.0x, 239.3x, 610.xx, 611.xx
Prostatectomy	Procedure codes: 60.2x, 60.3x, 60.4x, 60.5x, 60.6x Principal diagnosis codes: 185.xx, 600.xx

* The symbol "x" in a code indicates a blank or any number between 0 and 9.

Equations were derived to compute the probability of dying before discharge for each patient undergoing a procedure included in this study. Risk factors considered for each procedure were patients' age, sex, principal and secondary diagnoses, and selected information about procedures (eg, laparoscopic vs abdominal surgery). To identify potential risk factors, stepwise logistic regression⁸ was applied to New York's Statewide Planning and Research Cooperative System (SPARCS) data for 1996 and 1997. This state database was used exclusively to screen potential risk factors because, unlike the Medicare database, it distinguishes valid risk factors (ie, secondary diagnoses present on admission) from complications that occurred during hospitalization. Only comorbid conditions found to be statistically significant predictors of inpatient mortality (ie, $P < .05$) were selected as candidates for inclusion in final risk-adjustment equations. Finally, secondary diagnoses coded more frequently as complications than as comorbid conditions were eliminated from consideration, even if they were significant predictors of inpatient mortality. Final clinical risk-adjustment models were derived on the Medicare database by applying stepwise logistic regression to select statistically significant risk factors ($P < .05$).⁸ Bootstrapping techniques⁹ were used to ensure that the final variables

Table 2. Number of cases eliminated from model creation and mortality analysis

Total eligible cases	586,422
Cases with invalid provider codes	2,961
Remaining eligible cases	583,461
Cases coded as emergency	964
Remaining eligible cases	582,497
Cases in hospitals having <15 such operations in 3 y	24,292
Remaining eligible cases	558,205
Cases with no Medicare Part B data	28,627
Total cases used to create models	529,578
Cases with no anesthesia bill	48,316
Remaining eligible cases	481,262
Cases with ambiguous provider codes	27,981
Remaining eligible cases	453,281
Cases with incomplete billing or probably team care	49,087
Total cases included in analysis of mortality rates	404,194

were applicable to the entire range of observed data.

Institutional and geographic variables that might affect predicted mortality also were evaluated using stepwise logistic regression. Hospitals' number of beds, average daily census, total number of inpatient operations, percentage of registered nurses, and teaching status (ie, member of Council of Teaching Hospitals, residency program, or nonteaching hospital) were obtained from the 1997 American Hospital Association (AHA) Annual Survey Database. Hospitals' locations were characterized by state and rural-urban continuum codes (from the AHA database). Each hospital's relative volume of each operation was ranked in quartiles. The degree of a hospital's technological sophistication was ranked according to the following set of mutually exclusive categories: very high (ie, has burn or transplant unit), high (ie, has at least 2 of the following: trauma unit, cardiac catheterization laboratory, lithotripter, radiation therapy), moderate (ie, has at least 1 of the 4 services listed for the high category), low (ie, has magnetic resonance imaging, positron emission tomography, or single photon emission tomography scanning), or absent (ie, has none of the services mentioned).

The final risk-adjustment model contained each patient's predicted mortality rate from the appropriate clinical model and coefficients for the hospital characteristics that added significant predictive power, ie, relative volume of each operation, number of inpatient operations, average daily census, and the hospital's position on the rural-urban continuum. *C* statistics¹⁰ (ie, areas under receiver-operating characteristic curves) were calculated to assess each model's predictive power (ie, 1.0 equals perfect prediction, 0.5 equals no predictive power).

After development of risk-adjustment models, the database was refined further by excluding cases that had no bill for anesthesia services, had ambiguous anesthesia provider codes, or had bills that suggested team care but lacked corresponding bills for both an anesthesiologist's and a CRNA's services. Table 2 shows numbers excluded for these reasons.

Initial patient-specific mortality predictions were computed using procedure-specific risk-adjustment equations; predicted values then were adjusted using hospital-specific variables. The resulting predicted values were used to compare inpatient mortality rates among the 3 types of providers (anesthesiologists alone, CRNAs alone, anesthesia care teams).

The organization of anesthesia practice in a hospital may contribute to surgical outcomes regardless of which type of anesthesia provider cares for an individual patient. To assess whether differences in the

organization of anesthesia practice affected inpatient mortality rates, hospitals were categorized as having only 1 type of anesthesia provider (A1, A2, A3), having only solo practitioners (B), having a single type of solo practitioner and team anesthesia care (C1, C2), or having both types of solo practitioners and team anesthesia care (D).

We computed ² statistics to evaluate differences in distributions of cases among types of anesthesia providers and to examine the relation between types of providers and risk-adjusted inpatient mortality rates.¹¹

Results

For the 404,194 cases analyzed, Table 3 shows the distribution of patients among the 8 operations and the unadjusted mortality rate for each operation. Mortality rates ranged from 0.11% for mastectomies and for hysterectomies to 1.20% for cholecystectomies. The average for all patients was 0.38%. Anesthesia care was provided by anesthesiologists alone in 33.2% of cases, by CRNAs alone in 8.2%, and by anesthesia care teams in 58.6% (Table 4).

Table 5 presents the distribution of operations among the 22 states, from 0.6% in Delaware to 13.7% in Michigan. The percentage of cases in which anesthesiologists worked alone ranged from 5.3% in South Dakota to 84.3% in Washington. The percentage in which CRNAs worked alone ranged from 0% in Delaware to 33.6% in Kansas. The percentage of cases receiving care from teams ranged from 5.4% in New Mexico to 85.7% in North Dakota. Almost half the operations were performed within metropolitan areas of 100,000 to 1,000,000 residents (Table 6). Approximately one fourth were performed in metropolitan areas exceeding 1,000,000 residents. Almost 80% of operations in which CRNAs alone provided anesthesia were performed at rural hospitals or in metropolitan areas of fewer than 100,000 residents.

Table 7 lists *C* statistics for the 8 clinical risk-adjustment models and for the final model incorporating clinical risk and hospital characteristics. Patient factors were most predictive of mortality for patients undergoing cholecystectomy or herniorrhaphy and least predictive for patients undergoing mastectomy or knee replacement.

Table 8 presents risk-adjusted mortality rates by type of anesthesia provider and by hospitals' types of anesthesia practice. There were no significant differences in risk-adjusted mortality rates by type of anesthesia provider or by type of anesthesia practice within the hospital. These findings were not altered when risk-adjustment was performed using equations without hospital or geographic variables.

Table 3. Distribution of cases and unadjusted mortality rates, by procedure

Procedure	No.	% of Total*	Dead	% of Total*	% Dead
Carotid endarterectomy	56,957	14.09	282	18.18	0.50
Cholecystectomy	54,673	13.53	655	42.23	1.20
Herniorrhaphy	15,779	3.90	65	4.19	0.41
Hysterectomy	30,567	7.56	35	2.26	0.11
Knee replacement	111,124	27.49	256	16.51	0.23
Laminectomy	28,999	7.17	67	4.32	0.23
Mastectomy	27,418	6.78	31	2.00	0.11
Prostatectomy	78,677	19.47	160	10.32	0.20
Total	404,194	99.99	1,551	100.01	0.38

* Column totals do not equal 100.00% because of rounding.

Table 4. Number and percentage of cases receiving anesthesia from each type of provider, by procedure

Procedure	All cases		Anesthesiologist		CRNA		Team	
	No.	%*	No.	%	No.	%	No.	%
Carotid endarterectomy	56,957	14.09	22,164	38.91	1,495	2.62	33,298	58.46
Cholecystectomy	54,673	13.53	20,211	36.97	7,147	13.07	27,315	49.96
Herniorrhaphy	15,779	3.90	5,010	31.75	1,041	6.60	9,728	61.65
Hysterectomy	30,567	7.56	9,234	30.21	2,676	8.75	18,657	61.04
Knee replacement	111,124	27.49	33,341	30.00	9,617	8.65	68,166	61.34
Laminectomy	28,999	7.17	9,248	31.89	841	2.90	18,910	65.21
Mastectomy	27,418	6.78	8,342	30.43	2,435	8.88	16,641	60.69
Prostatectomy	78,677	19.47	26,785	34.04	7,899	10.04	43,993	55.92
Total	404,194	99.99	134,335	33.24	33,151	8.20	236,708	58.56

* The column total does not equal 100.00% because of rounding.

Discussion

Although there is a large body of literature delineating patient and hospital factors related to risk-adjusted surgical mortality,¹²⁻¹⁶ few studies have addressed the effect of the type of anesthesia provider on these outcomes.

A classic study of anesthesia-related mortality by Beecher and Todd⁴ more than 50 years ago found substantially higher mortality rates when anesthesia was administered by anesthesiologists than when it was administered by CRNAs. Because the physical status of patients treated by both types of providers was similar (according to American Society of Anesthesiologists' classifications), the researchers attributed the difference in outcomes to greater but unmeasured complexity of anesthesiologists' cases.

Two decades later, a North Carolina study⁵ found "the incidence [of death] among the three major groups (the CRNA, the anesthesiologist, and the combination of CRNA and anesthesiologist) to be rather similar...." However, provider-specific mortality rates in this study could not be risk adjusted because clinical data on surviving patients were unavailable.

Another study published in 1980⁶ compared risk-adjusted mortality (both surgical and anesthesia-related) at 9 hospitals "in which anesthesiologists primarily were the providers" with that at 7 hospitals "in which nurse anesthetists were primarily the providers." These authors concluded that "using conservative statistical methods, ... there were no significant differences in outcomes between the two groups

Table 5. Number and percentage of cases in each state, by type of anesthesia provider

State	All cases		Anesthesiologist		CRNA		Team	
	No.	%	No.	%	No.	%	No.	%
Alabama	26,699	6.61	4,328	16.21	1,242	4.65	21,129	79.14
Delaware	2,272	0.56	1,260	55.46	0	0.00	1,012	44.54
Idaho	7,663	1.90	1,738	22.68	1,701	22.20	4,224	55.12
Kansas	17,417	4.31	4,309	24.74	5,853	33.61	7,255	41.65
Louisiana	18,475	4.57	3,984	21.56	1,472	7.97	13,019	70.47
Maine	6,907	1.71	2,800	40.54	387	5.60	3,720	53.86
Michigan	55,485	13.73	14,721	26.53	3,425	6.17	37,339	67.30
Minnesota	19,481	4.82	1,311	6.73	2,361	12.12	15,809	81.15
Mississippi	15,205	3.76	6,506	42.79	520	3.42	8,179	53.79
Missouri	30,177	7.47	10,181	33.74	2,701	8.95	17,295	57.31
Montana	5,976	1.48	4,668	78.11	860	14.39	448	7.50
Nebraska	10,461	2.59	4,453	42.57	2,883	27.56	3,125	29.87
New Hampshire	4,498	1.11	2,056	45.71	273	6.07	2,169	48.22
New Mexico	6,514	1.61	4,293	65.90	1,869	28.69	352	5.40
North Carolina	34,811	8.61	4,739	13.61	610	1.75	29,462	84.63
North Dakota	4,480	1.11	451	10.07	190	4.24	3,839	85.69
Pennsylvania	54,563	13.50	25,055	45.92	312	0.57	29,196	53.51
South Carolina	17,474	4.32	7,382	42.25	448	2.56	9,644	55.19
South Dakota	6,312	1.56	335	5.31	704	11.15	5,273	83.54
Tennessee	28,837	7.13	9,599	33.29	4,035	13.99	15,203	52.72
Washington	21,904	5.42	18,455	84.25	1,109	5.06	2,340	10.68
West Virginia	8,583	2.12	1,711	19.93	196	2.28	6,676	77.78
Total	404,194	100.00	134,335	33.24	33,151	8.20	236,708	58.56

of hospitals defined by type of anesthesia provider.”

In an article that its authors confessed “lacks the scientific credibility of a review or original article and is related to policy making more than science,”¹⁷ Abenstein and Warner¹⁸ reinterpreted the findings of previous researchers. They concluded: “When the data are critically examined, the evidence is very supportive that the anesthesiologist-led anesthesia care team is the safest and most cost-effective method of delivering anesthesia care.” However, they presented no original data to support this conclusion.

In a more recent risk-adjusted study of 217,440 surgical cases in Pennsylvania, Silber et al⁷ observed an increase of 2.5 deaths per 1,000 patients when an anesthesiologist was not involved in the case. This statistic is alarming in light of the Institute of Medicine’s review, which concluded: “today, anesthesia mortality rates are about one death per 200,000-

300,000 anesthetics administered...”¹ However, approximately two thirds of cases classified by Silber et al⁷ as lacking an anesthesiologist either had no bill at all for anesthesia care or had an anesthesiologist involved in some but not all of a patient’s procedures. Cases in which an anesthesiologist worked alone were not distinguished from those in which anesthesia was provided by a team. And only cases in Pennsylvania were studied.

The present study endeavored to avoid these limitations by drawing cases from 22 states, including Pennsylvania. Only cases with clear documentation of type of anesthesia provider were included. Team care was distinguished from anesthesiologists or CRNAs practicing alone. Because patient and surgical risk far outweigh anesthesia risk in hospitalized patients undergoing surgical procedures^{14,19} and because risk adjustment using administrative data sets always is

Table 6. Distribution of cases among providers by size of metropolitan area where they worked

Metropolitan population	All cases		Anesthesiologist		CRNA		Team	
	No.	%	No.	%	No.	%	No.	%
>1,000,000	106,479	26.34	32,001	30.05	1,914	1.80	72,564	68.15
100,000-1,000,000	189,270	46.83	68,397	36.14	5,414	2.86	115,459	61.00
<100,000	108,445	26.83	33,937	31.29	25,823	23.81	48,685	44.89
Total	404,194	100.00	134,335	33.24	33,151	8.20	236,708	58.56

suboptimal,⁸ only surgical procedures that are performed on relatively homogeneous populations were included. Exclusion of emergency and other higher risk operations substantially reduced variability in predicted outcomes that can confound analyses, particularly when observational data sets are as unbalanced as the one used in this study. Also, because substantial differences in the risk of adverse outcomes remain even within these relatively homogeneous surgical categories, risk-adjustment equations were derived to account for any coexisting clinical conditions that might affect surgical mortality.

Particularly in high-risk emergency patients like those included in the study by Silber et al,⁷ a large proportion of postoperative deaths are attributable to patients' underlying conditions rather than to deficiencies in anesthesia care.^{14,19} The present study's focus on nonemergency procedures greatly increased the probability that coexisting serious acute conditions were not present at the time of operation. However, because deaths due to surgical complications generally are far more frequent than those due to anesthesia complications,^{14,19} even rigorous risk adjustment performed for a diverse set of surgical procedures across a widely dispersed geographic area probably failed to remove all systematic biases. Only a careful review of medical records to determine the actual causes of mortality and morbidity could eliminate these biases.

In the present study, patients were attributed to an anesthesia provider based on data from the operation that qualified them for inclusion in the study. In contrast, Silber et al⁷ classified cases as "undirected" if an undirected CRNA administered anesthesia for post-surgical palliative procedures, even when an anesthesiologist or a team administered anesthesia for the original surgical interventions. This difference in assignment may account, at least in part, for the higher risk-adjusted mortality rates observed by Silber et al⁷ in undirected cases.

It is important to note several limitations associ-

Table 7. C statistics for risk-adjustment models

Procedure	C statistic
Carotid endarterectomy	0.826
Cholecystectomy	0.883
Herniorrhaphy	0.853
Hysterectomy	0.811
Knee replacement	0.766
Laminectomy	0.787
Mastectomy	0.667
Prostatectomy	0.812
All + hospital characteristics	0.857

ated with any study that compares mortality rates using Medicare and AHA data.

First, non-Medicare cases are not in the database. Also, information about practitioners reflects only services that were billed, and there are no records of services for patients in Medicare health maintenance organizations.

Second, because Medicare data do not distinguish between valid risk factors (ie, comorbid conditions) and inpatient complications, risk adjustment using Medicare data may fail to capture the true preoperative risk of death.^{8,20} To enhance further the validity of risk-adjustment models, the present study limited risk variables to those identified using New York's SPARCS database, which distinguishes clearly between comorbid conditions and complications.

Third, information in the AHA database comes from hospitals themselves and is not validated independently. Consequently, this database, although used widely in research studies, may contain inaccuracies about some hospitals. For example, high technology reported by a small rural hospital may actually reside in an affiliated urban medical center 100 miles away, or "number of beds" may include some that were closed years ago.

Table 8. Risk-adjusted mortality rates by type of anesthesia provider

Type*	AA	CRNA	Team	No. of Hospitals	Cases per hospital	No. of cases	Dead	Predicted dead	Observed rate (%)	Predicted rate (%)	O/P
All cases											
A1	1			95	313	29,718	121	115.4	0.41	0.39	1.049
A2		1		191	71	13,592	61	68.0	0.45	0.50	0.897
A3			1	25	333	8,330	24	28.9	0.29	0.35	0.830
B	1	1		112	203	22,770	94	92.8	0.41	0.41	1.013
C1	1		1	574	457	262,289	978	982.0	0.37	0.37	0.996
C2		1	1	9	94	844	4	3.2	0.47	0.38	1.250
D	1	1	1	171	390	66,651	269	260.8	0.40	0.39	1.031
Total				1,177	343	404,194	1,551	1,551.0	0.38	0.38	1.000
Anesthesiologist only											
A1	1			95	313	29,718	121	115.4	0.41	0.39	1.049
B	1	1		112	107	11,970	52	50.1	0.43	0.42	1.037
C1	1		1	574	127	73,046	323	325.6	0.44	0.45	0.992
D	1	1	1	171	115	19,601	108	90.5	0.55	0.46	1.194
Total				952	141	134,335	604	581.6	0.45	0.43	1.039
CRNA only											
A2		1		191	71	13,592	61	68.0	0.45	0.50	0.897
B	1	1		112	96	10,800	42	42.6	0.39	0.39	0.985
C2		1	1	9	18	164	2	0.9	1.22	0.55	2.222
D	1	1	1	171	50	8,595	46	35.0	0.54	0.41	1.316
Total				483	69	33,151	151	146.5	0.46	0.44	1.031
Anesthesia care team											
A3			1	25	333	8,330	24	28.9	0.29	0.35	0.830
C1	1		1	574	330	189,243	655	656.3	0.35	0.35	0.998
C2		1	1	9	76	680	2	2.3	0.29	0.34	0.870
D	1	1	1	171	225	38,455	115	135.4	0.30	0.35	0.849
Total				779	325	236,708	796	822.9	0.34	0.35	0.967

* Key to types

A1 = Anesthesiologist as sole provider

A2 = CRNA as sole provider

A3 = Team as sole provider

B = Both anesthesiologist and CRNA, each working alone

C1 = Anesthesiologist alone and team care

C2 = CRNA alone and team care

D = Both types of solo providers and team care

AA indicates anesthesiologist alone; O/P, observed/predicted ratio; CRNA, Certified Registered Nurse Anesthetist.

Finally, the Medicare database does not permit precise identification of the cause of death. Detailed reviews of large numbers of medical records would be required to determine definitively the contribution of anesthesia care to operative and postoperative deaths.

After adjustment for differences in case mix, clinical risk factors, hospital characteristics, and geographic location, the current study found similar risk-adjusted mortality rates whether anesthesiologists or CRNAs worked alone. Furthermore, hospitals without anesthesiologists had results similar to those of hospitals in which anesthesiologists provided or directed anesthesia care. Anesthesia care teams had a slightly lower risk-adjusted mortality rate than did practitioners working alone, but the difference was not statistically significant. Although these findings differ from those of Silber et al,⁷ they are more consistent with the earlier research cited and with current data on overall anesthesia-related mortality.¹ They indicate that for the surgical procedures included in this study, the type of anesthesia provider does not affect inpatient surgical mortality.

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Anesthesiologist Direction and Patient Outcomes

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Background: Anesthesia services for surgical procedures may or may not be personally performed or medically directed by anesthesiologists. This study compares the outcomes of surgical

patients whose anesthesia care was personally performed or medically directed by an anesthesiologist with the outcomes of patients whose anesthesia care was not personally performed or medically directed by an anesthesiologist.

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Methods: Cases were defined as being either "directed" or "undirected," depending on the type of involvement of the anesthesiologist, as determined by Health Care Financing Administration billing records. Outcome rates were adjusted to account for severity of disease and other provider characteristics using logistic regression models that included 64 patient and 42 procedure covariates, plus an additional 11 hospital characteristics often associated with quality of care. Medicare claims records were analyzed for all elderly patients in Pennsylvania who underwent general surgical or orthopedic procedures between 1991-1994. The study involved 194,430 directed and 23,010 undirected patients among 245 hospitals. Outcomes studied included death rate within 30 days of admission, in-hospital complication rate, and the failure-to-rescue rate (defined as the rate of death after complications).

Results: Adjusted odds ratios for death and failure-to-rescue were greater when care was not directed by anesthesiologists (odds ratio for death = 1.08, $P < 0.04$; odds ratio for failure-to-rescue = 1.10, $P < 0.01$), whereas complications were not increased (odds ratio for complication = 1.00, $P < 0.79$). This corresponds to 2.5 excess deaths/1,000 patients and 6.9 excess failures-to-rescue (deaths) per 1,000 patients with complications.

Conclusions: Both 30-day mortality rate and mortality rate after complications (failure-to-rescue) were lower when anesthesiologists directed anesthesia care. These results suggest that surgical outcomes in Medicare patients are associated with anesthesiologist direction, and may provide insight regarding potential approaches for improving surgical outcomes. (Key words: Anesthesiologists; anesthesia care team; quality of care; mortality; failure-to-rescue; complication; Medicare; general surgery; orthopedics.)

AS hospitals and physicians adapt to new financial challenges, the mix of healthcare providers has been changing. Throughout the healthcare system, there are examples of work traditionally performed by specialists that is now allocated to generalists or nonphysicians. Many of the decisions regarding provider mix have been driven by financial considerations or provider availability, rather than by patient outcome data, which would be valuable for such decision-making. There are limited outcome data regarding provider models in specific ar-

ANESTHESIOLOGIST DIRECTION AND PATIENT OUTCOMES

eas, such as adult primary care office practice.¹ However, generalizations among specialties and provider types may not be valid because of differences in the intensity of the care rendered, the severity of illness of the patient, or the extent of the intervention, among others. Large-scale outcome data regarding the meaningful involvement of the anesthesiologist in surgical outcomes are few, yet the delivery of anesthesia services provides a unique opportunity to observe the influences of provider mix on outcomes in a complex medical environment. Anesthesiologists and nurse anesthetists have worked together or separately for many years, in a variety of provider models, ranging from independent practice to the "anesthesia care team" model.²

This study seeks to determine whether general and orthopedic surgical outcomes differ depending on whether the anesthesiologist is involved significantly in the delivery of anesthesia services to elderly Medicare patients. The answer to this question could have a significant impact on overall healthcare delivery because each year approximately 1.3 million Medicare beneficiaries are admitted to United States hospitals for orthopedic and general surgical procedures that necessitate anesthesia.³

Materials and Methods

Data

All Pennsylvania Medicare claims records for patients 65 yr or older were analyzed for general and orthopedic surgical admissions between 1991 and 1994. The study involved 194,430 "directed" and 23,010 "undirected" patients in 245 hospitals. Outcomes studied included death rate within 30 days of admission, in-hospital complication rate, and the failure-to-rescue rate (defined as the rate of death after complications). We obtained the Medicare Standard Analytic Files for all general surgical and orthopedic DRGs (diagnosis-related groups) in Pennsylvania between 1991 and 1994 (Medicare Part A data). For each patient we created a longitudinal record by appending all medical and surgical inpatient and outpatient claims and physicians' claims (Medicare Part B data) during that time interval. Data also included the American Hospital Association Annual Surveys for 1991-1993, and the Pennsylvania Health Care Cost Containment Council Data Base for years 1991-1994.

Patient Selection

We developed predictive models for a random sample of 50% of Medicare patients who underwent general

Table 1. DRGs Included in Dataset

General Surgical DRGs	Orthopedic DRGs
146 & 147; 148 & 149; 150 & 151; 152 & 153; 154 & 155; 157 & 158; 159 & 160; 161 & 162; 164 & 165; 166 & 167; 170 & 171; 191 & 192; 193 & 194; 195 & 196; 197 & 198; 199 & 200; 201; 257 & 258; 259 & 260; 261; 262; 263 & 264; 265 & 266; 267; 268; 286; 287; 288; 289; 290; 291; 292 & 293; 285	209; 210 & 211; 213; 214 & 215; 216; 217; 218 & 219; 221 & 222; 223 & 224; 225; 226 & 227; 228 & 229; 230; 231; 232; 233 & 234

For DRG 483 (tracheostomy), we reassigned the DRG that would have been assigned using the primary procedure code had a tracheostomy not been performed.

DRG = diagnosis-related group.

surgical or orthopedic procedures in Pennsylvania between 1991-1994 and tested our results on the other 50%. Final results are reported regarding the full sample of 217,440 individual patients. The DRGs included in this study are listed in table 1. The first hospital admission for any one of these DRGs triggered the identification of a study hospital admission.

Definitions

During the years discussed in this study, the Healthcare Financing Administration (HCFA) required that anesthesia care be either medically directed or supervised by a physician (supervision is defined as a level of physician participation that is less than that defined by medical direction). According to HCFA, the supervisor or director must have been a licensed physician, but not necessarily an anesthesiologist.⁴ To bill for medical direction, as defined by HCFA,⁵ physicians must have met all the criteria listed in table 2. Otherwise, the level of involvement was defined as "supervision" and physicians received markedly reduced payment.

Cases billed to Medicare as "personally performed" or directed by an anesthesiologist were defined in this study as directed. Otherwise, cases were defined as undirected.

Personally performed cases also included those in which an anesthesiology resident was directed by an attending anesthesiologist. (Anesthesiologist cases in which residents were directed were billed as personally performed for the first 3 yr of the study interval, and changes in the HCFA guidelines caused direction of

Table 2. Definition of Anesthesia Direction

Personal medical direction by a physician may be paid if the following criteria are met:

- No more than 4 anesthesia procedures are being performed concurrently.
- The physician does not perform any other services (except as provided below) during the same time period.
- The physician is physically present in the operating suite.
- The physician:
 - performs a pre-anesthetic examination and evaluation prescribes the anesthesia plan
 - personally participates in the most demanding procedures in the anesthesia plan, including induction and emergence
 - ensures that any procedure in the anesthesia plan that he or she does not perform are performed by a qualified individual
 - monitors the course of anesthesia administration at frequent intervals
 - remains physically present and available for immediate diagnosis and treatment of emergencies
 - provides indicated post anesthesia care.

Medicare Medical Policy Bulletin. Medical Direction of Anesthesia Services. Bulletin No. A-7A, January 1, 1994.

resident cases to be billed as "directing 2-4 cases" in the final year of the study.)

There were 23,010 patients defined as undirected in this study, of which 14,137 patients (61% of the undirected group) were not billed for anesthesia and 8,873 (39%) were billed for anesthesia. The "no-bill" cases were defined as undirected because there was no evidence of anesthesiologist direction, despite a strong financial incentive for an anesthesiologist to bill Medicare if a billable service had been performed. The cases in which an anesthesiology bill was not submitted showed billing data that indicated that a surgical procedure on our study list was performed. These cases either were supervised by a physician or a staff nurse anesthetist employed directly by the hospital or they represented undirected anesthesiology resident cases. Of these 14,137 no-bill cases, only 1,287 at most were anesthesia resident cases (or 5.6% of all undirected cases), assuming all no-bill cases at institutions with anesthesia residency programs reflected resident cases. The remaining undirected cases consisted of 8,873 patients (39% of the undirected group) for which procedures were supervised but not directed by an anesthesiologist or directed by a nonanesthesiologist physician. None of these cases included residents. Billing codes included "unknown physician specialty" (code 99) or "unknown provider" (code 88) associated with a nurse anesthetist specialty code 43 or nonanesthesiologist physician direction of the nurse anesthetist, including many other specialty

designations, such as pathology (code 22) or general medicine (code 11). Of the 217,440 patients, 20,066 (9.9%) patients underwent anesthesia procedures on more than 1 day during their hospital stay. We labeled a patient undirected if on any day of the hospital stay, all anesthesia procedures performed that day were not directed by an anesthesiologist.

In HCFA billing records the specialty code for anesthesiologist is denoted by an "05" designation. Anesthesiologist designation did not imply board certification. We used information from the American Board of Medical Specialties (ABMS) to verify Medicare data. In one instance, Medicare data indicated that the directing physician was a nonanesthesiologist, yet that same physician was noted to be board certified in anesthesiology according to the American Board of Medical Specialties files. We therefore recoded that person as an anesthesiologist for our purposes.

Outcome Statistics

Death within 30 days of admission was determined from the HCFA Vital Status file. Complications (table 3) were identified using a set of 41 events defined by

Table 3. Complications: Defined Using ICD-9-CM and CPT Codes

Cardiac event (e.g., serious arrhythmia)	Perforation
Cardiac emergency (e.g., cardiac arrest)	Peritonitis
Congestive heart failure	GI or internal bleed
Postoperative cardiac complications	Sepsis
Hypotension/shock	Deep wound infection
Pulmonary embolus	Renal dysfunction
Deep vein thrombosis	Anesthesia event
Phlebitis	Gangrene of extremity
Stroke/CVA	Intestinal obstruction
TIA	Return to surgery
Coma/other	Decubitus ulcer
Seizure	Orthopedic complication
Psychosis	Compartment syndrome
Nervous system complications	Malignant hyperthermia
Pneumonia—Aspiration	Hepatitis/jaundice
Pneumonia—Other	Pancreatitis
Pneumothorax	Necrosis of bone/thermal
Respiratory compromise	or aseptic
Bronchospasm	Osteomyelitis from
Postoperative respiratory complications	procedure
Internal organ damage	Fat embolism
	Electrolyte/fluid abnormality

The algorithms for constructing the complications using ICD-9-CM and CPT codes are available upon request.

CPT = Physician's Current Procedural Terminology, 4th edition; CVA = cerebral vascular accident; GI = gastrointestinal; ICD-9-CM = International Classification of Diseases, 9th revision, Clinical Modification; TIA = transient ischemic attack.

ANESTHESIOLOGIST DIRECTION AND PATIENT OUTCOMES

International Classification of Diseases, 9th revision, Clinical Modification (ICD-9-CM) and CPT (Physician's Current Procedural Terminology, 4th edition) codes available from HCFA databases for the hospital stay of interest, previous hospital stays, and outpatient visits within 3 months before the index hospital stay. CPT codes billed before the hospital stay were used to determine long-standing conditions that would aid in distinguishing complications from comorbidities. Failure-to-rescue rate (FR) was defined as the 30-day death rate in those in whom either a complication developed or who died without a recorded complication. It can be expressed mathematically as follows: $FR = D / (C + D | no C)$ or the number of patients who died (D) divided by the number of patients with complications (C) plus the number of patients who died without complications noted in the claims data (D|no C).^{6,7}

Estimates of excess deaths/1,000 patients were derived using a direct standardization approach using the full data set for both the directed and the undirected cases.⁸ Using the final fully adjusted model, the probability of death was estimated twice for each of the 217,440 patients in the study, once assuming each case was undirected and once assuming the case was directed. The resultant difference between the sum of the estimated death rates, divided by the sample size, and multiplied by 1,000, provides the number of excess deaths/1,000 patients when cases are not directed. The same method was used to estimate the excess number of failure-to-rescue cases in the undirected group, except the denominator of cases includes only those with complications. The advantage of this standardization approach is that all patients are used for both estimates, hence reducing bias.

Model Development and Validation

We developed three logistic-regression models to adjust for severity of illness and case mix, one for each outcome in the 50% random or "development" sample. Candidate variables were selected if significant at the 0.05 level after univariate analysis for any of the three outcomes. DRG variables were grouped into DRG-principal procedure categories to produce more homogeneous risk groupings based on Haberman residuals^{7,9,10} and then included in each model. Each model included 42 DRG-principal procedure variables and 27 patient characteristics. A total of 37 interaction terms were included in the models, having been significant at the Bonferroni adjusted 0.05 level. We validated the derived models for the remaining 50% or "validation" sample.

Coefficients were not statistically different between models derived in development and validation sets. Pearson correlation coefficients between predicted outcomes in the development set and the validation set were always greater than 0.93. Final models were constructed using both the development and the validation data sets.

Hospital Analyses

To account for hospital characteristics that may have influenced our results, we adjusted the results using a list of 11 hospital characteristics that we, and others, reported previously.^{7,11,12} Further, we constructed an indicator variable for each hospital and report results adjusted for each individual hospital in the logistic-regression modeling. We also performed adjustments for each hospital using Mantel-Haenszel tests¹³ in a number of ways. We estimated the odds ratio (OR) associated with outcome and no direction by controlling for each hospital and stratified, in some analyses, using the risk of death or the propensity score¹⁴⁻¹⁸ to predict lack of direction. When stratifying using the risk of death, we refitted the mortality model, deriving new coefficients, using a separate data set of 1995-1996 Pennsylvania Medicare patients. This allowed for unbiased odds ratios derived from the Mantel-Haenszel tests when applied to the main study set comprising 1991-1994 data.

Results

Patient Description

Table 4 describes patient case mix and table 5 displays patient characteristics that were present in at least 1% of the study population among the anesthesia directed and nondirected groups. Two odds ratios are presented in table 5. The first is the unadjusted odds ratio; the second is the Mantel-Haenszel¹³ odds ratio after adjusting for DRG category and each of the 245 hospitals in the study. Undirected patients were more likely to be male; to have a history of arrhythmia, congestive heart failure, and non-insulin-dependent diabetes; and to be admitted through the emergency department. Undirected patients were less likely to have cancer.

There were some associations between covariates and direction status that were unexpected. Some of these could be explained when we studied factors that were predictive of direction¹⁴ and factors predictive of procedures. For example, the unadjusted odds ratios in table 5 suggest undirected cases had greater odds of occurrence

Table 4. Medical Diagnostic Categories (MDC) by Direction Status

	Directed		Not Directed	
	N	%	N	%
MDC 6 Diseases and disorders of the digestive system (146 & 147; 148 & 149; 150 & 151; 152 & 153; 154 & 155; 157 & 158; 159 & 160; 161 & 162; 164; 165; 166; 167; 170 & 171)	54,443	28.00	6,805	29.57
MDC 7 Diseases and disorders of the hepatobiliary system (191 & 192; 193 & 194; 195 & 196; 197 & 198; 199 & 200; 201)	24,957	12.84	3,429	14.90
MDC 8 Diseases and disorders of the musculoskeletal system (209; 210 & 211; 213; 214 & 215; 216; 217; 218 & 219; 221 & 222; 223 & 224; 225; 226; 227; 228 & 229; 230; 231; 232; 233 & 234; 257 & 258; 259 & 260; 261; 262; 263 & 264)	111,825	57.51	12,141	52.76
MDC 9 Diseases and disorders of the skin, subcutaneous tissue, and breast (265 & 266; 267; 268)	392	0.20	86	0.37
MDC 10 Endocrine, nutritional, metabolic diseases and disorders (285; 286; 287; 288; 289; 290; 291; 292 & 293)	2,813	1.45	549	2.39
Total	194,430	89.42	23,010	10.58

in patients with insulin-dependent diabetes. However, undirected patients also had greater odds of undergoing wound debridement and skin grafts as a principal procedure, as compared with directed patients (OR = 10.14; 95% confidence interval [CI] = 8.31, 12.36). The higher rate of diabetes in the undirected group may, in part, have been caused by an increased propensity of the caregiver to perform skin graft procedures, and therefore it would not be surprising that there was an association between undirected cases and diabetes. Bickel *et al.*¹⁹ have shown the importance of such adjustments when making inferences concerning selection bias in

graduate school admissions policies. Hence, after adjustment, it would appear as though there was far less imbalance in the covariates between directed and undirected cases than was initially appreciated. However, given the remaining differences between groups, careful severity corrections for all outcomes were performed before results could be accurately interpreted.

Hospital Characteristics

The distribution of hospital characteristics according to the presence of anesthesiologist direction is displayed in table 6. Generally, the hospitals in which undirected

Table 5. Comparison of Patient Characteristics (Odds Ratio for Undirected versus Directed Cases)*

	Percent of Total Population	Unadjusted		Adjusted by DRG and Hospital	
		Odds Ratio	P Value	Odds Ratio	P Value
Age older than 85 yr	9.9	1.048	0.040	1.044	0.110
Male	34.7	1.122	0.001	1.053	0.002
Hx congestive heart failure	2.6	1.637	0.001	1.159	0.001
Hx arrhythmia	2.9	1.357	0.001	1.092	0.001
Hx aortic stenosis	1.8	0.979	0.689	0.996	0.946
Hx hypertension	6.6	1.202	0.001	1.017	0.578
Hx cancer	24.2	0.900	0.001	0.903	0.001
Hx COPD	12.1	1.093	0.001	1.024	0.312
Hx noninsulin-dependent diabetes	10.6	1.293	0.001	1.074	0.003
Hx insulin-dependent diabetes	1.7	2.163	0.001	1.046	0.387
Emergency department admission	34.4	1.232	0.001	1.247	0.001

* Odds ratio denotes the odds of a covariate of interest observed in the undirected group versus that of the directed group.

COPD = chronic obstructive pulmonary disease; Hx = history.

ANESTHESIOLOGIST DIRECTION AND PATIENT OUTCOMES

Table 6. Distribution of Hospital Characteristics by Type of Provider

Hospital Characteristics	Undirected	Directed	P Value
No. of beds greater than 200 (%)	32.72	42.49	0.0001
Nurse-to-bed ratio (RNs/bed)	1.38	1.40	0.0001
Percentage of anesthesiology staff board certified (%)	72.70	74.70	0.0001
Percentage of surgical staff board certified (%)	80.40	85.00	0.0001
Trauma Center (%)	21.87	23.90	0.0001
Lithotripsy facility (%)	17.55	15.68	0.0001
MRI facility (%)	33.27	35.90	0.0001
Solid organ/kidney transplant (%)	11.99	13.56	0.0001
Bone marrow transplant unit (%)	5.37	7.22	0.0001
Approved residency training program (%)	40.90	49.20	0.0001
Member, Council of Teaching Hospitals (%)	17.87	21.89	0.0001

MRI = magnetic resonance imaging; RN = registered nurse.

cases occurred tended to be smaller, to have less specialized technology and facilities, and were less likely to be involved with the teaching of medical students and residents.

Adjusting for Patient Characteristics and DRG-Procedure Category

Unadjusted death, complication and failure-to-rescue rates were greater when cases were undirected (table 7). Table 8 displays the influence of anesthesia direction on outcome after results were adjusted for 64 patient characteristics and interaction terms, including demographic information, history variables, whether the patient was transferred from another short-term-care hospital, whether the patient was admitted from the emergency room, and 42 DRG—procedure categories used for this study. As in the unadjusted model, mortality and failure-to-rescue rates were greater when an anesthesiologist did not perform or direct care. The adjusted odds ratios for death and failure-to-rescue were significantly increased: (OR for death = 1.09, $P < 0.021$; OR for failure-to-rescue = 1.12, $P < 0.003$) corresponding to 2.8 excess deaths/1,000 patients and 8.4 excess deaths/1,000 patients with complications. Adding patient race to this model did not change these results.

A second analysis was performed adding admission MedisGroups (MediQual Inc., Westborough, MA) sever-

ity score (a physiologic based score) obtained from the Pennsylvania Health Care Cost Containment Council.^{6,20-23} During 1991-1994, MedisGroups scores were recorded for only 72.9% of our study patients. The ORs for the anesthesia direction covariate were as follows: (OR for death = 1.09, $P < 0.016$; OR for failure-to-rescue = 1.12, $P < 0.002$; OR for complication = 0.97, $P < 0.052$). These results provided further evidence that the models derived solely from the Medicare data were adequately adjusted.

We also explored whether the increased odds of death and failure-to-rescue in the undirected group were caused by admissions through the emergency department. When the non-emergency department cases were analyzed separately, the odds ratios for death and failure-to-rescue remained greater for those patients who did not receive anesthesiologist direction (adjusted OR for death = 1.17, $P < 0.007$ and adjusted OR for failure-to-rescue = 1.18, $P < 0.005$).

Adjusting for Patient and Hospital Characteristics

The lower portion of table 8 displays the results of anesthesia direction when 11 hospital variables were included in the three outcomes models. Undirected cases were associated with greater death and failure-to-rescue rates: (OR for death = 1.08, $P < 0.040$; OR for failure-to-rescue = 1.10, $P < 0.013$), corresponding to

Table 7. Unadjusted Outcomes

Outcome	Undirected Rate (%) n = 23,010	Directed Rate (%) n = 194,430	Odds Ratio*	95% Confidence Interval	P Value
Death	4.53	3.41	1.35	(1.26, 1.44)	0.0001
Complication	47.87	41.15	1.31	(1.28, 1.35)	0.0001
Failure to rescue	9.32	8.18	1.15	(1.08, 1.24)	0.0001

* Odds ratio denotes the odds of an outcome observed in the undirected group versus that of the directed group.

Table 8. Logistic Regression Results

Events	No. of Patients	No. of Events	C Statistic	Adjusted Odds Ratio*	95% Confidence Interval	P Value
Adjusting for patient characteristics						
Death	217,440	7,665	0.82	1.09	(1.01, 1.17)	0.0208
Complication	217,440	91,024	0.75	0.97	(0.94, 1.00)	0.0345
Failure-to-rescue	92,170	7,665	0.75	1.12	(1.04, 1.21)	0.0025
Adjusting for patient and hospital characteristics						
Death	217,440	7,665	0.82	1.08	(1.00, 1.15)	0.0399
Complication	217,440	91,024	0.75	1.00	(0.96, 1.03)	0.7941
Failure to rescue	92,170	7,665	0.75	1.10	(1.01, 1.18)	0.0128

* Odds ratio denotes the odds of an outcome observed in the undirected group versus that of the directed group.

2.5 excess deaths/1,000 patients and 6.9 excess deaths/1,000 patients with complications, whereas the adjusted OR for the complication rate was insignificant (OR for complication 1.00, $P < 0.796$). When the MedisGroups severity score was added to the analysis, death and failure-to-rescue ORs were stable and the associated P values became slightly more significant. When a variable reflecting the number of anesthesia procedures per hospital stay was added to the model, we again found the odds ratio estimates to be unchanged.

In a further analysis, we calculated the adjusted odds ratios for each outcome using the Mantel-Haenszel odds ratio, adjusting for all DRG categories and for each of the 245 hospitals in the study, and obtained very similar results. The adjusted odds ratio for death was 1.14 ($P < 0.001$), the odds ratio for failure-to-rescue was 1.11 ($P < 0.008$), and the odds ratio for complication was 1.06 ($P < 0.001$). We next constructed a model adjusting for the same patient characteristics as in table 8 plus a hospital identifier variable for each hospital (grouping hospitals with fewer than 10 deaths into one indicator variable to allow for more stable coefficients). The results were almost identical to those in table 8. The adjusted odds ratio for death was 1.09 ($P < 0.033$), OR for failure-to-rescue was 1.10 ($P < 0.016$), and the OR for complication was 1.02 ($P < 0.333$).

Further Analyses Using Mantel-Haenszel Adjustments and the Propensity Score

We conducted an additional set of analyses concerning the influence of the hospital provider on outcome in this study. Using the full model for patient characteristics, as defined in table 8, we refitted the model coefficients for a separate set of 102,781 Pennsylvania Medicare patients from 1995 and 1996, using the same procedures as in the 1991-1994 study data set. We then calculated the initial risk of death before surgery for each patient in our

1991-1994 study data set and, as suggested by Cochran,²⁴ we divided these risk scores at the quintiles of this distribution, yielding five risk groups of equal sample size. For each of the 245 hospitals in the data set, we then formed $245 \times 5 = 1,225$ cells using these five risk groups. This gave us a $2 \times 2 \times 5 \times 245$ contingency table, recording death by direction status by mortality risk strata by hospital. The associated Mantel-Haenszel odds ratio computed from the $2 \times 2 \times 5 \times 245$ cell contingency table was 1.16 (1.077, 1.246). This ratio was almost exactly the same as the Mantel-Haenszel test results with an odds ratio of 1.14, controlling for the individual hospital and DRG (see previous section in Results), whereas the logit model using hospital indicators also found a very similar odds ratio (1.09). Hence, we obtained almost identical results when the ORs were derived from regression models or derived by performing a Mantel-Haenszel analysis, controlling for risk of death, and forcing all comparisons to be stratified within the same hospital, thereby controlling for the "hospital effect."

To control for selection bias associated with direction or lack of direction, we performed an additional set of analyses using the propensity score to predict direction. Similar to the stratification of mortality risk previously discussed, we divided the propensity score at the quintiles of its distribution, yielding five risk groups of equal sample size. For each of the 245 hospitals in the data set, we then formed a 2 (death status) $\times 2$ (direction status) $\times 5$ (propensity score risk strata) $\times 245$ hospital contingency table. The associated Mantel-Haenszel odds ratio computed from the $2 \times 2 \times 5 \times 245$ cell contingency table was 1.11 (1.03, 1.19). Again, the odds ratio for death associated with direction status was almost identical to that determined by our previous methods using logit regression or methods without the propensity score.

Finally, we performed an adjustment stratifying by mortality risk, propensity score, and hospital using a $2 \times$

ANESTHESIOLOGIST DIRECTION AND PATIENT OUTCOMES

Table 9. The Marginal and Partial Influence of Hospital Characteristics and of Direction of Anesthesia Care on Outcome, Adjusting for Patient Covariates

Variable	Outcome Measure	Adjusted Odds Ratios (95% Confidence Interval)	
		Marginal	Partial
Hospital beds (≥ 200 beds vs. < 200 beds)	Death	0.90 (0.86, 0.95) ^a	0.90 (0.84, 0.97) ^d
	Failure-to-rescue	0.83 (0.80, 0.88) ^a	0.87 (0.81, 0.94) ^f
	Complication	1.22 (1.20, 1.25) ^a	1.11 (1.08, 1.14) ^a
Registered nurse-to-bed ratio (in units of 25% of the mean)	Death	0.95 (0.93, 0.96) ^a	0.95 (0.92, 0.97) ^a
	Failure-to-rescue	0.94 (0.92, 0.96) ^a	0.95 (0.93, 0.98) ^a
	Complication	1.04 (1.03, 1.04) ^a	0.98 (0.98, 0.99) ^f
Magnetic resonance imaging facility	Death	0.96 (0.92, 1.01)	1.04 (0.98, 1.10)
	Failure-to-rescue	0.93 (0.89, 0.98) ^c	1.05 (0.99, 1.11)
	Complication	1.06 (1.04, 1.00) ^a	0.95 (0.93, 0.98) ^a
Bone marrow transplantation unit	Death	0.89 (0.80, 0.98) ^b	0.99 (0.88, 1.11)
	Failure-to-rescue	0.79 (0.72, 0.88) ^a	0.93 (0.82, 1.04)
	Complication	1.34 (1.29, 1.39) ^a	1.17 (1.12, 1.22) ^a
Organ transplantation unit	Death	0.91 (0.84, 0.98) ^c	1.03 (0.94, 1.12)
	Failure-to-rescue	0.83 (0.77, 0.89) ^a	0.97 (0.89, 1.07)
	Complication	1.26 (1.22, 1.29) ^a	1.12 (1.08, 1.16) ^a
Lithotripsy facility	Death	0.92 (0.86, 0.99) ^b	0.97 (0.90, 1.05)
	Failure-to-rescue	0.88 (0.82, 0.94) ^f	0.97 (0.89, 1.05)
	Complication	1.10 (1.07, 1.13) ^a	1.01 (0.98, 1.05)
Trauma center	Death	0.93 (0.88, 0.99) ^b	1.03 (0.96, 1.11)
	Failure-to-rescue	0.89 (0.84, 0.95) ^a	1.05 (0.98, 1.34)
	Complication	1.10 (1.08, 1.13) ^a	0.94 (0.91, 0.97) ^a
Surgical board certification, % (in units of 25% of the mean)	Death	0.97 (0.94, 1.00) ^f	0.99 (0.96, 1.03)
	Failure-to-rescue	0.94 (0.91, 0.98) ^a	0.98 (0.95, 1.02)
	Complication	1.07 (1.05, 1.08) ^a	1.03 (1.01, 1.04) ^f
Anesthesia board certification, % (in units of 25% of the mean)	Death	0.99 (0.97, 1.01)	1.01 (0.99, 1.03)
	Failure-to-rescue	0.97 (0.95, 0.99) ^d	1.00 (0.98, 1.02)
	Complication	1.05 (1.04, 1.05) ^a	1.01 (1.00, 1.02) ^d
Member, Council of Teaching Hospitals	Death	0.91 (0.85, 0.96) ^d	1.03 (0.94, 1.12)
	Failure-to-rescue	0.84 (0.79, 0.89) ^a	1.02 (0.93, 1.11)
	Complication	1.26 (1.23, 1.29) ^a	1.10 (1.06, 1.14) ^a
Approved residency training program	Death	0.94 (0.89, 0.98) ^c	1.03 (0.97, 1.11)
	Failure-to-rescue	0.87 (0.83, 0.91) ^a	0.99 (0.93, 1.06)
	Complication	1.21 (1.18, 1.23) ^a	1.07 (1.04, 1.10) ^a
Anesthesiologist-directed care ^a	Death	0.92 (0.85, 0.99) ^c	0.93 (0.87, 1.00) ^b
	Failure-to-rescue	0.89 (0.83, 0.96) ^d	0.91 (0.85, 0.99) ^b
	Complication	1.04 (0.87, 1.07)	1.00 (0.97, 1.04)

^a < 0.1; ^b < 0.05; ^c < 0.01; ^d < 0.005; ^e < 0.001; ^f < 0.0005; ^g < 0.0001.

Odds ratio denotes the odds of an outcome observed in the directed group versus that of the undirected group.

Marginal analysis reports the odds ratios associated with hospital characteristics added one at a time in the logit model that includes 64 patient and 42 procedure covariates and interaction terms.

Partial analysis reports the odds ratios associated with hospital characteristics added all together to the logit model that includes 64 patient and 42 procedure covariates and interaction terms.

2 × 5 × 5 × 245 cell contingency table. Mortality risk was again estimated for the separate 1995–1996 patient population to avoid bias. This analysis yielded, again, similar results to the logit model reported in table 8, with an OR of 1.07, (0.99, 1.15). The slightly less significant *P* value of 0.09 may reflect the fact that we were controlling for 5 times more strata than in the previous two analyses.

Table 9 displays the results of the “fully adjusted patient

model,” with the addition of all 11 hospital characteristics and the direction indicator for the three outcomes. For each hospital variable, and the anesthesiologist direction indicator, we present two results. The “marginal” result is computed by adjusting the OR for direction by all patient covariates and a single hospital variable or direction indicator. The “partial” analysis displays the results of a fully adjusted model using all patient covariates, all hospital covariates, plus the direction indicator (this “par-

tial" model is also shown in table 8). The marginal analysis showed that hospitals with more sophisticated facilities, higher nurse staffing ratios, and more educational programs were consistently associated with reduced death and failure-to-rescue rates, whereas complication rates were greater in these hospitals. We reported this same pattern in other studies.^{7,11,22} Simultaneously adjusting for all the hospital variables and the anesthesiologist direction variable, we found that three factors continued to show independent effects on death and failure-to-rescue: hospital size, nurse-to-bed ratio, and direction by an anesthesiologist.

Furthermore, we asked whether the odds ratios associated with direction and outcome would have changed had we used only patients who were billed, rather than all records. The resulting logistic-regression derived odds ratios were unchanged. Finally, we asked whether adding variables denoting the size of the metropolitan area would account for the observed differences in outcome. Adjusting for the 11 hospital variables and for five levels of population size from rural to metropolitan areas greater than 1 million, we found very little difference in results (OR for death = 1.07, $P < 0.057$; OR for failure-to-rescue = 1.09, $P < 0.021$; OR for complication = 1.00, $P < 0.853$).

Discussion

After adjustments for severity of illness and other confounding variables, we found higher mortality and failure-to-rescue rates for patients who underwent operations without medical direction by an anesthesiologist. Adjusted complication rates were not associated with medical direction. This finding is not inconsistent with the finding of higher mortality rates in the absence of medical direction. Our previous work showed that complication rates, as reflected in administrative claims data, are indicators of severity of illness,^{7,11,22} but adjusted complication rates are not well-correlated with adjusted death rates.^{11,22,23} In Medicare surgical patients, complication rates are poor indicators of quality of care^{6,7} and are not accurately coded to discern specific intraoperative events. The complication rate in this study reflects the number of patients who had complications, not the number of complications per patient. The complication list was developed to be inclusive and sensitive to most undesirable occurrences during the hospital stay, but was not specific for perioperative complications. Specific perioperative complications may not appear in the

Medicare claims data, in which the limited number of fields and variation in recording patterns may prevent the complication rate from reflecting differences in quality. Hence, it is not surprising that adjusted complication rates were not different among providers, whereas 30-day mortality rate—a measure better defined and recorded—was different.

Because of these limitations in all studies involving the Medicare database, the failure-to-rescue rate was developed and validated,^{6,7} and complications were used as an adjustment tool for severity of illness, rather than as an isolated outcome measure. Failure-to-rescue assesses how complications are managed by studying the rate of death only in those patients in whom complications develop or in those who die without recorded complications. Failure-to-rescue may provide better insight regarding quality of care than either mortality or complication rates used alone^{6,7} because it can more easily account for differences in severity. For the current study, failure-to-rescue rates showed an even greater association with provider characteristics than did death rates. This suggests that advanced medical training may allow for better management of complications, thereby decreasing the severity of such complications, and leading to fewer subsequent deaths.

Adequate severity adjustment is always necessary for studies of the type reported herein. Given the apparent difference in the prevalence of specific comorbidities between the directed and undirected groups, adequate adjustment was especially important. As seen in table 5, much of the difference between groups could be explained by the different distribution of procedures found in the directed and undirected groups. Hence, looking at unadjusted prevalence rates of comorbidities can be deceiving in data sets such as this. A classic example of this same problem was provided by Bickel *et al.*¹⁹ in their 1975 article of graduate admission bias using data from The University of California at Berkeley. Although unadjusted admission acceptance rates would suggest females had been discriminated against because of the observed overall lower admission rates, after adjustment for the departments to which the female students applied, it was shown that there was no significant bias. This was because the female applicants more often applied to departments with lower rates of acceptance (for both males and females), whereas male applicants more often applied to departments with higher rates of acceptance (for both males and females). Hence, the overall, unadjusted numbers suggested an imbalance in admission rates (a bias against females), whereas such an

imbalance was not seen at the individual department level.

It was reassuring that, in our study, after adjustment for DRG and hospital, the difference in the prevalence of covariates between the directed and undirected groups became much smaller. In part, this was caused by a tendency for undirected patients to be involved with slightly more minor procedures in patients with a greater number of comorbidities. Although adjustments in table 5 helped to explain these differences in comorbidity rates among groups, more complete model-based adjustments were made when reporting final results.

There is strong supporting evidence that the model-based adjustments used in our study were adequate. Of interest, unadjusted rates of death, number of complications, and failure-to-rescue rates were all increased in the nondirected group. After using models that contained identical patient covariates for each of the three outcomes, we observed that the adjusted odds of development of complications decreased to 1, whereas ORs of death and failure-to-rescue remained greater than 1. Further, the unadjusted OR associated with no direction and failure-to-rescue (table 7) was almost identical to that in the fully adjusted model (table 8). This finding is consistent with a number of studies showing that a strength of the failure-to-rescue concept is that the failure-to-rescue rate appears to be less sensitive to omissions of severity of illness data than is the death or complication rate.^{7,22} Finally, when a physiologic severity adjustment measure, MedisGroups Score, was added to the models, results were virtually unchanged. If the association between anesthesiologist direction and outcome was an artifact of failure of the model to adequately control for critical aspects of patient severity, we would have expected the addition of the physiologic-based patient severity score to alter the results. Together, these findings provide consistent supporting evidence that the model was adjusted adequately for severity of illness among groups.

Without further adjustment, these results might still reflect differences in overall hospital quality, rather than differences in the type of anesthesiologist involvement. Therefore, the results were simultaneously adjusted for patient and hospital characteristics, yet the effect of anesthesiologist direction remained significant. When we adjusted for the individual hospital using Mantel-Haenszel adjustments and logistic-regression models, our results were unchanged. Further, adjustments for selection bias using the propensity score again revealed that our results were very stable. It appeared that the increased risk of death associated with lack of direction

was not caused by selection bias at the hospital. Thus, these data support the concept that there is a benefit associated with medical direction by an anesthesiologist that is independent of the hospital effect and not a result of selection bias.

Our results were consistent with other large studies of anesthesia outcomes.^{25,26} Some studies suggest that the best outcomes may occur when anesthesia is provided by an anesthesia care team directed by an anesthesiologist.²⁷ We also found that the single most important hospital variable associated with lower death and failure-to-rescue rates was a higher registered-nurse-to-bed ratio,⁷ and the importance of nurse staffing has been noted in several other studies.^{7,28-30}

Our results also point to a common misconception when assessing anesthesia safety. Since the early (1954) study of Beecher and Todd³¹ reported an anesthesia-related mortality rate of 1 death/1,560 patients, anesthesia-related mortality has been the gold standard of gauging anesthesia safety. By 1982, the anesthesia-related mortality had decreased to 1 death/6,789 patients in the United Kingdom,³² and, by 1989, the anesthesia mortality rate had decreased to 1 death/185,056 patients³³; whereas Eichhorn,³⁴ in 1989, reported anesthesia-related mortality of 1 death/151,400 patients among more than 750,000 healthy (American Society of Anesthesiologists physical status I or II)³⁵ patients in the United States. These studies supported the concept that the incidence of death directly related to anesthetic events had decreased, but the concept of anesthesia-related mortality was narrowly defined. Modern perioperative intensive care (including that provided by anesthesiologists) often prevents immediate postoperative mortality, yet prolonged morbidity and delayed mortality may result even when the precipitating event occurred preoperatively or intraoperatively. Further, there is increasing evidence that anesthetic practice influences subsequent patient outcomes in ways that were not recognized previously. Even relatively simple measures, such as maintaining normothermia or supplying supplemental oxygen in the perioperative period, can decrease the incidence of subsequent morbid events, including perioperative cardiac morbidity (ischemia, infarction, cardiac arrest),³⁶ and postoperative wound infection.^{37,38} Our study underscores the importance of anesthetic practice in overall surgical outcome, potentially influencing mortality at the rate of 2.5 deaths/1,000 patients or 1 death/400 patients, more than 300 times greater than reported by Eichhorn³⁴ and others,^{32,33} who used a far

more narrow definition of "anesthesia related" that did not consider these wider associations.

This was a retrospective analysis based on administrative claims data and is limited by the associated errors inherent in using such data. The accuracy of our definitions for anesthesiologist direction (or no direction) is only as reliable as the bills (or lack of bills) submitted by caregivers. We also cannot rule out the possibility that unobserved factors leading to undirected cases were associated with poor hospital support for the undirected anesthesiologist and patient. Local, temporal, even psychologic factors may play a part in patient outcome, and such factors may not be noted in the available data set. For example, if anesthesiologists had a tendency not to submit bills for patients who died within 30 days of admission, our results could be skewed in favor of directed cases. Although our clinical experience suggests that this scenario is quite unlikely, we cannot rule out this possibility. We also cannot rule out the possibility that undirected cases occur more often in emergency situations that developed outside of the emergency department. For example, it may be that patients who required multiple anesthesia procedures were more ill and were cared for by an undirected anesthesiologist because of an emergency reoperation that did not allow time for the anesthesiologist to participate in care. Although we could find no evidence of this, because our study results were unchanged when a variable denoting multiple anesthesia procedures was added to the model, more extensive study involving individual chart review may be helpful for exploring these questions.

Future work will also be needed to determine whether the mortality differences in this report were caused by differences in the quality of direction among providers, the presence or absence of direction itself, or a combination of these effects. To address these limitations, we hope to pursue in-depth, large-scale medical chart review of surgical cases in the next phase of this research. We anticipate that review of medical charts will provide more detailed information that will assist in determining the etiology of differences in outcomes among provider type.

In summary, review of Medicare claims data in Pennsylvania suggests that medical direction by an anesthesiologist was associated with lower mortality and failure-to-rescue rates. In light of the large numbers of Medicare patients undergoing operations each day, future research must carefully identify the etiologic factors associated with these findings to define optimal provider models and improve outcomes.

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ANESTHESIOLOGIST DIRECTION AND PATIENT OUTCOMES

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 416, 482, and 485

[HCFA-3049-F]

RIN 0938-AK08

Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services.

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the Anesthesia Services Condition of Participation (CoP) for hospitals, the Surgical Services Condition of Participation for Critical Access Hospitals (CAH), and the Ambulatory Surgical Center (ASC) Conditions of Coverage Surgical Services. This final rule changes the physician supervision requirement for certified registered nurse anesthetists furnishing anesthesia services in hospitals, CAHs, and ASCs. Under this final rule, State laws will determine which professionals are permitted to administer anesthetics and the level of supervision required, recognizing a State's traditional domain in establishing professional licensure and scope-of-practice laws. States and hospitals are free to establish additional standards for professional practice and oversight as they deem necessary.

The hospital anesthesia services CoP, CAH surgical services CoP, and the conforming change to the anesthesia Conditions of Coverage apply to all Medicare and Medicaid participating hospitals, CAHs, and ASCs.

EFFECTIVE DATE: These regulations are effective on March 19, 2001.

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I. Background

A. Legislation

Sections 1861(e)(1) through (e)(8) of the Social Security Act (the Act) provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861(e)(9) of the Act specifies that a hospital also must meet such other requirements as the Secretary finds necessary in the interest of the health and safety of the hospital's patients. Section 1820 of the Act contains criteria for application for States establishing a Critical Access Hospital. Sections 1832(a)(2)(F)(i) and 1833(i) provide coverage requirements for ASCs. Section 1861(bb) of the Act, provides definitions for certified registered nurse anesthetists (CRNAs) and their services.

B. General

On December 19, 1997, we published the proposed rule, "Hospital Conditions of Participation, Provider Agreements and Supplier Approval," (62 FR 66726) in the **Federal Register**. This proposed rule generated over 60,000 public comments and approximately one-third of these comments addressed the proposed condition eliminating the Federal requirement for physician supervision of a licensed independent practitioner permitted by the State to administer anesthetics.

In 1997, when we proposed our changes to the current hospital conditions of participation (CoPs), we stated our desire to move toward standards that are patient-centered, evidence-based, and outcome oriented. We also stated that a fundamental principle was to facilitate flexibility in how a hospital meets our performance expectations, and eliminate structure and process requirements unless there is evidence that they are predictive of desired outcomes for patients. Where there is agreement on a structure or process requirement predictive of desired patient outcomes, we included that in our proposed rule. In fact, comments on the standard for physician

supervision of CRNAs reflect a split between those who support flexibility in allowing States and hospitals to make decisions about anesthesia services and those who oppose the provision, supporting, instead, the structural requirement for physician supervision. We have already finalized the Organ Donation and Transplantation and Patients' Rights conditions, which were contained in the December 19, 1997 proposed hospital rule. We are now finalizing part of the anesthesia services standard describing anesthesia administration. We continue to work to finalize the other issues in the December 19, 1997 hospital conditions of participation proposed rule.

C. Need for Amended Anesthesia Services CoP

The existing hospital CoPs require hospitals, CAHs, and ASCs to provide quality care by adhering to our organizational and staffing requirements. The current hospital CoPs are not written in a way that promote or encourage a hospital, CAH, or ASC to assess the quality of care and improve patient outcomes. One of the clear messages we received from industry groups and professionals as we pursued this change in regulatory approach is that the old way of focusing on structure and process no longer represented current practice or the best available method to foster delivery of quality health care services.

Since publication of the December 19, 1997 proposed rule, we have continued to receive input from representatives of individual industry groups and have analyzed thousands of public comments from individual providers, beneficiaries, hospitals, and professional and provider organizations. We have given careful consideration to the scientific literature cited by commenters. We have found no compelling scientific evidence that an across-the-board Federal physician supervision requirement for CRNAs leads to better outcomes, or that there will be adverse outcomes by relying on State licensure laws instead.

We are also responding to considerable Congressional activity that has occurred since the 1997 publication of the proposed rule. Interest by Congress on both sides of the issue of physician supervision resulted in Appropriations Conference committee language in the Conference Report to the Balanced Budget Refinement Act (BBRA) of 1999 (H. Conf. Rep. No. 106-

479, at 873 (November 18, 1999)) urging the Secretary to determine whether there was sufficient information to move forward with a final rule. The literature we reviewed (see appendix) indicated that the anesthesia-related death rate is extremely low, and that the administration of anesthesia in the United States is safe relative to surgical risk.

There have been no studies published within the last 10 years demonstrating any need for Federal intervention in State professional practice laws governing CRNA practice. Currently, there is no reason to require a Federal rule in these conditions of participation mandating that physicians supervise the practice of another State-licensed health professional where there is a statutory provision authorizing direct Medicare payment for the services of that health professional. We believe there is no reason to change our proposed approach, which gives States and hospitals the flexibility to determine necessary oversight. We believe the change, based on the available information, appropriately reflects the important value of regulatory flexibility.

D. Recognizing State Laws and Professional Scope of Practice

Congress has specified which non-physician health professionals may receive separate payment for their professional services (such as CRNAs and nurse practitioners). In addition, Congress left the function of licensing these health professionals to the States. Medicare recognizes the scope of practice established by the States for these health professionals. Prior to this final rule, Medicare's hospital CoPs did not have Federal requirements for physicians to supervise the practice of another State-licensed health professional where there is a statutory provision authorizing direct Medicare payment for the services of that health professional, with the sole exception of the Federal requirement for physician supervision of CRNAs. We do not believe that there is evidence to support maintaining a special Federal requirement for physician supervision of CRNAs.

Eliminating the Federal requirement for physician supervision of CRNAs is not a judgment on our part that one health professional is better than another or that one type of care is superior. The change in regulatory approach reflected in this final rule was discussed in the preamble of the hospital CoPs proposed rule (62 FR 66740). This rule establishes a shared commitment to quality care among us, the States, and Medicare providers.

Medicare providers are in the best position to assess the evidence and consider data relevant to their own situations (for example, physician access, hospital and patient characteristics and needs of rural areas) about the best way to deliver anesthesia care. Hospitals can always exercise stricter standards than required by State law. We will monitor the effects on the quality of anesthesia care furnished to Medicare beneficiaries resulting from the greater flexibility provided to States and hospitals under this rule.

II. Analysis of and Responses to Public Comments

We received approximately 20,000 comments on the issue of physician supervision of CRNA administration of anesthesia. Comments were largely split among CRNAs, representatives of rural areas, and supporters of State oversight who favor the proposal; and physicians who, in general, opposed the proposal and argued that anesthesia administration is the practice of medicine, requiring advanced medical education. A summary of the major issues and our responses follow:

State Law and Professional Scopes of Practice

Comment: The majority of comments focused on whether States' scope-of-practice laws are the proper level of regulatory oversight. Most physicians maintained that anesthesia is the practice of medicine which should only be practiced by a licensed physician, and opposed the provision permitting State licensed independent practitioners to administer anesthetics without physician supervision. These commenters argued that, because of disparities among the various States, laws are inconsistent and result in inequality of care across the country. As a result, they stated that Medicare beneficiaries would lose an important Federal guarantee for minimum standards of anesthesia care, and instead would be subjected to a variety of State laws. Conversely, other commenters argued that the Federal rule preempts State law, creating barriers to practice and limiting opportunity for nurse anesthetists licensed as independent practitioners. A physician supervision requirement, they asserted, diminishes the role of local jurisdictions and authorities that regulate and/or license other health professions and aspects of health service delivery. Commenters also stated that the current Federal requirement for physician supervision has been a disincentive for employers to hire CRNAs, decreasing flexibility and efficiency in anesthesia

services, and limiting access in certain areas. One commenter wrote that it is the State that best understands its individual geographical, population, and financial needs and resources and how these resources can best be utilized to deliver safe, quality anesthesia services.

Response: We respect the authority of States to meet regional/local needs. Setting forth a final rule that allows States the ultimate determination regarding which licensed independent practitioners may administer anesthesia does not prohibit any State or hospital from requiring physician supervision. It will effectively provide greater discretion to State authorities that are experienced at regulating the licensing, education, training, and skills of the professionals practicing under their purview, without the burden associated with duplicative regulatory oversight. There is no evidence that States are less concerned with ensuring safety and quality than the Federal government, especially where the health of their citizens is at stake. We disagree that States are less capable or less committed to protecting patients and ensuring quality anesthesia services than the Federal government. The final rule removes the "across the board" Federal requirement for physician supervision in every case of anesthesia administration. At the same time, it broadens overall flexibility by permitting individuals and authorities closer to patient care delivery to make decisions about the best way to deliver health care services.

Comment: Some commenters were concerned that this change in regulatory approach would grant the right to practice medicine to individuals who were not properly prepared to do so. One commenter pointed out that we were giving unsupervised privileges to prescribe narcotics, paralytic agents, and cardiac drugs to people who have neither a medical license nor the training and credentialing that is associated with a medical license.

Response: States regulate professionals who may prescribe medicines as well as which medical procedures may be performed under a professional license through their professional practice laws. Our regulations do not determine prescribing authority or grant medical licenses, and this final rule does not change the traditional purview under which these professional scope-of-practice issues have occurred in the past. The final rule does not prohibit physicians from practicing medicine, nor does it allow nurse anesthetists to practice beyond the scope of their

practice or authority granted them by States.

Comment: We received several comments from both physicians and nurse anesthetists in support of allowing physicians, hospitals, and surgical centers more responsibility for the care they furnished. Some commenters noted that the medical staffs within institutions should determine guidelines for supervision of all health care personnel contributing to the medical care of patients. Several commenters recognized the value of allowing hospital boards and medical staffs to set the standards of care. These commenters thought that relying on greater accountability from doctors and hospitals instead of Federal regulation would lead to better care for patients. Commenters noted that this rule would allow hospitals to set standards different from us, based on review and input from physicians and other health professionals. The American Hospital Association (AHA) also supported this rule change, stating "This new policy ensures that only personnel trained in administering anesthesia are allowed to do so. This requirement balances accountability with flexibility."

Response: We agree that providers have a shared responsibility, with us and the States, to assure quality standards of practice. We are pleased that the hospital industry recognizes the values of accountability and flexibility in Federal regulation. Allowing States to make determinations about health care professional standards of practice, and hospitals to make decisions regarding the delivery of care, assures that those closest to, and who know the most about, the health care delivery system are accountable for the outcomes of that care.

Comment: Several commenters stated that the administration of anesthesia has never been exclusively the practice of medicine. These commenters noted that anesthesia administration is within the scope of practice of nurses, physicians, dentists, podiatrists, and other professionals who have been properly educated and credentialed in the field of anesthesia. Since more surgical procedures are moving out of the hospital into clinic and office settings, an institution needs the flexibility to utilize the anesthesia professional of its choice which best matches the needs of the patient.

Response: Although this final rule governs anesthesia administration in hospital, CAH, and ASC settings only, we agree with the need for flexibility in other settings, especially as surgical techniques, methods for administering

anesthesia and the availability of drugs is improved.

We believe that the range of patient types, surgical procedures, new technologies, and provider settings (for example, hospital outpatient departments, intensive care units, and teaching hospitals) makes an across-the-board Federal requirement overly burdensome. Differences between a healthy young patient undergoing minor surgery in a hospital outpatient department and a medically compromised, elderly patient undergoing major surgery in a large teaching facility are so great that a single Federal requirement is not applicable in every situation.

Comment: Several commenters objected to our arguments that eliminating CRNA supervision would, "allow greater flexibility to hospitals and practitioners" and would "give deference to State scope-of-practice laws". These commenters believe that our reasoning is weak, especially in the absence of documentation that either of these issues is a problem.

Response: We disagree with these commenters. As previously noted, we respect State control and oversight of health care professionals by deference to State licensing laws which regulate professional practice. There is no reason to consider physician supervision of CRNAs a special case requiring a national standard. Advances in anesthesia and surgical techniques, the availability and discovery of new drugs, and the varying medical presentations of patients make it less prudent to rely on a single national standard requiring physician supervision of CRNAs to be applied in every situation. Doing so risks losing the accountability of practitioners, both to make clinical decisions based on the needs of patients, and to utilize resources effectively. We believe States need flexibility from Federal oversight of those processes, such as professional licensing, for which they are ultimately accountable. In fact, it is at the State level where much direct input by health professionals into scope-of-practice and licensing laws takes place.

Comment: One commenter asked what rule would be operative in the absence of any State law.

Response: The final rule allows only a licensed practitioner permitted by the State to administer anesthetics to do so. Therefore, State health professional practice laws, such as those covering nurse and physician practice, as well as hospital licensing requirements, would be the basis for determining which health care professionals can administer anesthesia in any given State.

Safety and Quality of Care

Comment: Many of the commenters who wrote expressing concern over quality of anesthesia services referred to published research to support their point of view. For example, many commenters who support the proposed rule stated that evidence shows anesthesia administered by CRNAs to be as safe as that administered by anesthesiologists. In contrast, we also received comments from anesthesiologists who noted positive patient outcomes from anesthesia administration to be related to the presence of the anesthesiologist. The articles most frequently cited by commenters were three by Jeffrey Silber, M.D. and colleagues (1992, 1995, 1997), and another by J.P. Abenstein and M.A. Warner (1996). Many commenters claimed these studies concluded either an anesthesiologist alone, or a CRNA in "collaboration" with an anesthesiologist, had better patient outcomes than a CRNA alone. Many commenters contend, erroneously, the recommendations from the Abenstein & Warner article were adopted by the Minnesota legislature (although it is not clear to what recommendations the commenters were referring). Many other commenters urged us not to consider the change made by this rule until there is solid, scientifically defensible outcome data to establish that independent nurse anesthesia care is just as safe as anesthesiologist care.

Response: The conclusions of the commenters were not supported by findings from the studies they cited, nor do the studies conclude that States provide inadequate oversight and that a Federal standard is therefore necessary. We reviewed available literature and found the following major conclusions (see appendix).

- All literature surveyed agreed that the anesthesia-related death rate is extremely low, and the administration of anesthesia in the United States is safe relative to surgical risk. In fact, according to the 1999 Institute of Medicine Report *To Err Is Human*, "anesthesia mortality rates are about one death per 200,000–300,000 anesthetics administered, compared with two deaths per 10,000 anesthetics administered in the early 1980s," a 40- to 60-fold improvement.

- There are no studies published within the last 10 years that are specific to the issue of the final rule, namely provision of anesthesia care by CRNAs practicing without physician supervision. All of the studies we reviewed had significant limitations. Conclusions are limited by these

studies' failure to control adequately for possible correlations among variables such as higher risk patients and hospital characteristics (for example, size and sophistication of medical technology) as they would affect deaths attributable to anesthesia.

- There is no evidence that there would be adverse outcomes by relying on States and hospitals to regulate the appropriate supervision and scope of practice of health professionals administering anesthesia. Nor has there been any evidence that States do a poor job in regulating and overseeing health care professional practice or that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another.

In the Silber studies, the authors did not conclude that CRNAs may be providing poor care that might more likely lead to negative outcomes. The 1992 study did not address whether there is an association between patient outcomes and the type of professional who furnished anesthesia. The anesthesia variable used in the study was not specific to the patient, rather it was a variable at the hospital level (for example, percent of anesthesiologists who are board-certified). The anesthesia variable might be a proxy indicator of quality of the hospital: Thus, there would be lower mortality in the higher quality hospitals and if a complication occurred the patient would more likely be rescued.

Silber urges "that the limitations of the project be recognized." The limitations include: There were relatively few deaths, adverse outcomes and failures, and relatively few patients per hospital so the rates could only be compared for groups of hospitals, not specific facilities.

In a subsequent article to the one summarized above, Silber and colleagues (1995) found that "most of the predictable variation in outcome rates among hospitals appears to be predicted by differing patient characteristics rather than by differing hospital characteristics, that is, by who is treated rather than by the resources available for treatment." The authors found higher proportions of board-certified anesthesiologists to be associated with lower death and failure rates, but also with higher adverse occurrence rates. The study did not address the relationship between the patient outcomes and the type of professional who furnished the anesthesia care. The study did not address the issue of provision of anesthesia care by CRNAs supervised and not supervised by physicians. The

article presents no information that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another. Silber and his colleagues (1997) have also conducted methodological studies that compare the usefulness of three outcome measures, mortality, complication and failure-to-rescue rates. They concluded that for the general surgical procedures studied, the complication rate is poorly correlated with the death and failure rate. The authors suggest that great caution be taken when using complication rates and that they should not be used in isolation when assessing hospital quality of care. The study did not address the relationship between the patient outcomes and the type of professional who furnished the anesthesia care. Nor did the study address the issue of provision of anesthesia care by CRNAs supervised and not supervised by physicians, the issue in the rule. The article presents no information that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another.

We have also reviewed a more recently published article by Dr. Silber (July 2000) and colleagues from the University of Pennsylvania. This article also is not relevant to the policy determination at hand because it did not study CRNA practice with and without physician supervision, again the issue of this rule. Moreover, it does not present evidence of any inadequacy of State oversight of health professional practice laws, and does not provide sound and compelling evidence to maintain the current Federal preemption of State law.

Even on its own terms, the study has the following methodological shortcomings:

- The study used a non-experimental research design and only examined claims data, instead of reviewing medical records or observing actual care. Even though the researchers statistically controlled for 106 proxy indicators of care, without a stronger research design, they can only make a weak conclusion about an "association" between a variable and an outcome.

- The study did not control for the cause of death. Cases where a patient died from an anesthesia related cause, the surgery itself, an unrelated medical error, or an unknown medical condition are all considered, regardless of the cause of death. Not having data on deaths actually attributed to anesthesia is problematic since the mortality data used covers any death occurring within

30 days of a hospital admission. Events occurring 30 days from admission cannot be attributed to the anesthesia care alone. While the researchers argue that "delayed" death (that is, within 30 days of admission) is the appropriate measure of mortality for anesthesia care, the study does not produce causal evidence for such a theory. At a minimum, the researchers could have presented results for mortality measured for shorter periods of time such as within 72 hours of admission which may or may not have shown different outcomes for short-term and delayed deaths.

- Both the study and comparison groups included cases where physicians supervised CRNAs and personally furnished anesthesia. (The study group also included cases where anesthesiologists medically directed residents). The purpose of the study was to examine differences when an anesthesiologist versus a non-anesthesiologist physician is involved in the case. One cannot use this analysis to make conclusions about CRNA performance with or without physician supervision.

- The study used data where anesthesia was furnished by unknown suppliers (incorrectly referred to in the article as "unknown providers") either personally providing care or supervising CRNAs. Because a supplier is not a physician there are likely to be data coding errors which could contaminate and bias the results.

Even if the methodological shortcomings were fixed, because the study did not address the issue in the final rule, it is inappropriate to impute results from this study to the issue in this final rule, the provision of care by CRNAs supervised and not supervised by physicians.

Even if the recent Silber study did not have methodological problems, we disagree with its apparent policy conclusion that an anesthesiologist should be involved in every case, either personally performing anesthesia or providing medical direction of CRNAs. Such a policy is much more restrictive than current Medicare policy because it would prohibit non-anesthesiologist physicians to supervise CRNAs. This would make it difficult to perform surgeries in many small and rural hospitals because anesthesiologists generally do not practice in these hospitals.

Finally, even if we were to consider that the Silber article should guide our policy, we note, that due to the difference between relative risk and absolute risk, the reported size-effect is too small to cause us to change our

decision. The Silber article reported an odds ratio for death of 1.08 corresponding to 2.5 excess deaths per 1000 cases (relative risk). However, due to the lack of medical record review in this study these excess deaths cannot be solely attributed to anesthesia care and thus is not the absolute risk. For example, if we accept the IOM review of the literature of 33.3–50 anesthesia related deaths per 10 million (i.e., one per 200,000–300,000) then the absolute risk of excess deaths would be in the range of 2.7–4.0 per 10 million (.08 times range of 33.3–50). This size of absolute risk must be balanced against the risk of death due to lack of timely access to anesthesia services because of a federal imposition of a supervision requirement. At a minimum States are certainly capable of balancing the risks of lack of supervision versus the shortage of anesthesiologists given the supply of anesthesiologists in each of their respective States.

The Abenstein & Warner (1996) paper describes a number of aspects of anesthesia care and reviews studies in several areas. The paper notes that there has been a dramatic improvement in anesthetic deaths in the last 15 years: "Since 1979, five studies have documented a remarkably abrupt decrease in anesthetic-related death rates, morbidity, and risk of perioperative deaths." The paper concludes that: For many patients, it is now as safe to be anesthetized as to be a passenger in an automobile."

The paper notes that "identifying the cause for the improvement in anesthetic outcome is as problematic as determining the cause of perioperative death." The paper indicates that "huge numbers of surgical patients (that is, >1,000,000) must be enrolled in studies to provide the statistical power needed to determine whether there are associations between perioperative disability or death and various anesthetic techniques, technologies, and practice models." The paper notes that studies of this size are expensive. None of the studies reviewed meet this standard.

The paper reviewed two studies that compared mortality for anesthesia care furnished by anesthesiologists, and anesthesia care team and nurse anesthetist supervised by a physician. Neither meets the criteria for an adequate study identified in the paper. As the authors note, the first study did not provide statistical analysis of the data. The second study used data now 25 years old and found no statistically significant difference between the groups. Neither study examined the provision of anesthesia furnished

independently by CRNAs, the issue of this rule.

The paper suggested a number of reasons for improved anesthesia care including "new and improved patient monitoring techniques." The paper also notes that the "decline in adverse outcomes occurred at the same time that the number of American trained physicians entering and graduating from anesthesiology residency programs more than doubled (1975–1985)." The paper suggests that "the increase in the number of physicians engaged in the practice of anesthesiology is primarily responsible for the dramatic improvement in perioperative outcomes." However, the paper also notes that during roughly the same period of time, 1970–1985, the number of active nurse anesthetists doubled.

On the basis of studies which are flawed methodologically, which do not prove causality, and which do not meet the authors' own criteria for rigorous study, the authors nevertheless conclude that "the presence of board-certified anesthesiologists has been associated with the decline in death and disability commonly attributed to adverse perioperative events." The authors' conclusion is not substantiated by their own review and analysis of the literature. Finally, the paper presents no information regarding the issue in the rule or that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another.

As part of the decision to finalize the rule, we considered the feasibility of conducting a study comparing the mortality and adverse outcomes of Medicare patients for anesthesia care furnished by CRNAs with and without physician supervision. However, we concluded that it was not feasible to conduct such a retrospective study. Not only would the low overall anesthesia mortality make it difficult to develop a sufficient sample, but because of the current Medicare rule, there are no cases where CRNAs practice without supervision and thus there would be no data for the key comparison. We also considered the feasibility of conducting a study using data from non-Medicare patients. However, because Medicare's current hospital conditions of participation apply to all patients, here too there would be no data for the key comparison. Finally, we do not believe that it would be wise to conduct a prospective demonstration which would waive State law and prospectively randomly assign patients to study and control groups because it would remove

patient choice of anesthesia professional.

Comment: Several commenters felt strongly that anesthesia should be considered a high-risk procedure where mistakes are measured in terms of death and injury. These commenters believe that millions of patients will be at a higher risk for injury without the supervision of board certified anesthesiologists. One commenter noted that without the requirement, no trained physician would be available to respond to any emergency during a case where a CRNA was practicing independently.

Response: If we were to require board certification for anesthesiologists as a hospital CoP it would be a stricter requirement than currently exists for the practice of any other medical specialty subject to our CoPs. Hospitals have been providing anesthesia care without a Federal requirement for board certified anesthesiologists since the inception of the Medicare program. This rule does not change the requirement that hospitals must have physicians available at all times and that all Medicare patients are under the care of a physician as defined in section 1861(r) of the Act. Therefore, the patient's medical and/or surgical care continues to be the responsibility of his or her assigned physician.

Comment: Several commenters wanted to know what had changed since a 1992 HCFA comment that, "In view of the lack of definitive clinical studies on this issue, and in consideration of the risks associated with anesthesia procedures, we believe it would not be appropriate to allow anesthesia administration by a nonphysician anesthetist unless under supervision by either an anesthesiologist or the operating practitioner."

Response: As discussed above, there are no definitive studies one way or the other which address this question. The studies we discussed in our 1992 final rule on fee schedules for CRNAs (57 FR 33878, July 31, 1992) have limitations, as does the literature since 1992. Moreover, there is no evidence that an across-the-board physician supervision requirement for CRNAs leads to better outcomes or that there will be adverse outcomes by relying on State licensure laws instead. What has changed since 1992 is our view that it is unnecessary to continue a special Federal preemption of State licensing laws regulating professional practice for CRNAs.

The 1999 IOM Report cites a drop in anesthesia mortality rates from two deaths per 10,000 anesthetics administered in the early 1980's to

about one death per 200,000 to 300,000 anesthetics administered today. Chassin (1998) identifies several studies which note this improvement is a result of "a variety of mechanisms, including improved monitoring techniques, the development and widespread adoption of practice guidelines and other systematic approaches to reducing error." This is an impressive improvement and confirms the soundness of the approach taken in this final hospital CoP, which broadens the flexibility for States and providers, who are much closer to the realities of patient care, to make decisions about the best way to improve standards and implement best practices.

Comment: Several commenters stated that quality of care should be an important consideration in determining the need for physician supervision. Some commenters noted an association between improved anesthesia outcomes and increased numbers of anesthesiologists practicing. Many commenters noted that some CRNAs could function independently, but that others lack the judgement and knowledge to safely provide anesthesia without supervision. Further, commenters point out that CRNAs are more than capable of administering anesthesia on a healthy adult; however, when a patient's health is poor, an anesthesiologist should be involved in the care. Some nurse anesthetists report concern with their ability to deal with anesthetic complications without the availability of an anesthesiologist.

Response: Our decision to change the Federal requirement for supervision of CRNAs applicable in all situations is because, as stated in the preamble of the proposed rule, we are committed to changing current regulations that focus largely on procedural requirements, such as the Federal regulation mandating physician supervision of CRNAs. These comments make clear there are a range of factors to be considered (for example, patient types, surgical procedures, technology, and provider settings). Differences between a healthy young patient undergoing minor surgery in a hospital outpatient department and a medically compromised, elderly patient undergoing major surgery in a large teaching facility are so great that a single Federal requirement applicable in every situation is not sensible.

Comment: One commenter noted that the practice of anesthesiology extends beyond the operating room to the Intensive Care Unit (ICU), pain management, and other medical consultation. The commenter believes that the removal of the medical

supervision requirement risks removing the anesthesiologist from the practice of anesthesia.

Response: The change in the physician supervision requirement for CRNAs does not affect the anesthesiologist's ability to provide services outside the operating room.

Comment: A few commenters told us they believed it was the Federal government's responsibility to set safety standards for the nation and this rule evades that responsibility. One commenter agreed that CRNAs have a good safety record, but emphasized that they have been under the direct supervision of the anesthesiologist. He believed that eliminating the supervision requirement would cause these positive patient outcomes to occur less frequently. Other commenters agreed that physicians absolutely need to be involved for the practice of medicine to be safe, and this regulation change is in direct violation of this principle. Some commenters noted that the practice of safe anesthesia administration is largely due to better monitoring techniques, technology, improved drugs, and not to greater supervision by a physician. One commenter stated that in combination with improved drugs and techniques, CRNAs will bring greater access to anesthesia services in situations and areas where they are currently limited in their practice because of the physician supervision requirement, thus allowing such delivery of medical services that improve patient health and safety, and provide services to a greater number of people.

Response: We are acutely aware that ensuring patient safety and high quality patient outcomes are the principal considerations in regulating providers. There is no indication that physician supervision of a CRNA affects such outcomes. It is for this reason that we are moving away from a focus on physician supervision, where there is no evidence or data linking this structural requirement to patient outcomes. As previously noted, changing the supervision requirement does not obviate the requirement that every Medicare patient admitted to the hospital be under the care of a physician or doctor of osteopathy. This requirement remains an important component in the hospital CoPs. Even under the current regulation CRNAs are not required to be under the supervision of an anesthesiologist; the operating physician can meet the rule's supervision requirement. This rule does not prohibit anesthesiologist supervision or administration; it simply

leaves the decision up to State law or hospital policy.

This rule recognizes the significant improvement in the safety of anesthesia administration made by improved technology and implementation of practice guidelines. As in other areas of health care, new drugs and pharmaceuticals have contributed to improved patient outcomes as well. This underscores the findings in our review of the literature that multiple variables, some interacting in combination with each other, contribute to anesthesia-related patient outcomes.

Comment: We received several comments from beneficiaries who had received anesthesia care from a CRNA and felt comfortable with the service that was provided. They describe their anesthesia experiences as compassionate and thorough, including quality service and attention from these professionals. Many felt their care was excellent. Another commenter noted nurse anesthetists take time to be compassionate and attentive to fears, approaching anesthesia care holistically.

We also received comments from beneficiaries who felt that their care was being compromised for economic reasons by not requiring a doctor to be in charge of their anesthesia. Many reported increased fears during a time when they are most vulnerable, without the guarantee that a doctor will be in charge of their anesthesia care. Many reported that, as senior citizens, they faced more complicated medical and surgical procedures than younger patients and therefore that hospitals should be required to have a doctor in charge of administering their anesthesia.

Response: Patient experiences can be influenced not only by the anesthetist, but the surgeon, the type of procedure, the emergency nature of the procedure, and other factors. We also believe that many Medicare beneficiaries have been receiving anesthesia from CRNAs without being specifically aware of the credentials of the administering professional. We agree that a patient's perception of the safety and concern demonstrated by medical personnel is important but there is no evidence linking safety or better patient outcomes to the Federal requirement for physician supervision.

The change made by this rule is not specific to the patient's status as a Medicare beneficiary but to the participation of the provider in the Medicare program. The increased flexibility gained by this rule will allow hospitals and doctors to make decisions, pursuant to State law, about what is best for patients, reinforcing the primacy of the doctor-patient relationship.

Professional Education and Training

Comment: Several commenters noted the differences in training and education between a CRNA and an anesthesiologist. These differences were considered significant by anesthesiologists, who believe that anesthesia administration is the practice of medicine and should only be performed by physicians. Physician commenters pointed out that anesthesiologists receive in-depth training in physiology, pharmacology, diagnosis, treatment and independent management of patient care. In addition, because they are physicians and have received medical training, anesthesiologists assess a patient's medical condition, as well as plan and administer the anesthetic. One physician stated "nurse anesthetists are trained to assist anesthesiologists; they are not physicians and are not trained in medical diagnosis and therapy. The lack of medical background prevents the CRNA from being able to diagnose and treat the unexpected, and often serious, reactions that can accompany anesthesia in even the simplest of cases. CRNAs should be considered valued extenders of care but not as substitutes for the expertise of an anesthesiologist." Other commenters stated that nurses are trained to follow orders and medical protocols, and are not trained to diagnose and treat. Several anesthesiologists, who had been nurse anesthetists, wrote describing that not until they had medical school training did they understand the full impact of the differences between the education preparing them as nurse anesthetists versus their preparation to practice as anesthesiologists. One commenter stated he believed the regulation should be based on demonstrated formal education. Another physician commenter stated he believed CRNAs were well educated and trained and had good records of performance, but that this was due to their collaboration with doctors, and not their independent management of medical situations.

Some commenters stated, inaccurately, that the postgraduate training of nurse anesthetists is unique in that, after a minimum of a bachelor's degree in nursing, the nurse anesthetist student is required to have at least two years of practical experience in a critical care setting before advanced formal education in anesthetic administration. They stated that this advanced training prepares the nurse anesthetist to provide the full range of anesthesia services, independently. Several commenters noted that nurse anesthetists must be board certified by

successfully completing the National Certification Examination. Other commenters felt that the knowledge and expertise in nurse anesthesia care is equivalent to the preparation provided physicians. Some commenters reminded us that the Federal supervision requirement has been the only obstacle to independent practice, and that otherwise nurse anesthetists are licensed and trained to practice independently. One CRNA stated he did not agree with the contention that educational differences between CRNAs and anesthesiologists are sufficient reasons to place practice restrictions on CRNAs.

Response: Education and training requirements for CRNAs vary among the States. Decisions about appropriate and necessary education and training for health professionals are made by States and educational institutions in compliance with education accreditation standards. Professional schools, both medical and nursing, are accredited by educational organizations with specific standards for curriculum content. Evidence of graduation from an accredited school is part of a State's licensing and certification requirements, independent of Federal regulation. Anesthesia administration by nurse anesthetists has a long history in this country, including a level of independent practice in Department of Defense hospitals. We cannot agree that anesthesia administration is the practice of medicine and therefore can only be done after medical school training. Moreover, the rule does not allow any provider to practice outside the parameters of his or her professional license.

We also believe that this rule is consistent with both sides of this argument as reflected in the comments. The added flexibility and shared responsibility allows each health professional to practice within his/her licensed scope of practice without an across-the-board Federal requirement limiting any collaborative, team or independent practice.

Comment: Additional commenters claimed significant variation among program requirements in nurse anesthetist training. Some of these commenters cited an article from the June 1996 Journal of the American Association of Nurse Anesthetists, identifying that more than one-third (37 percent) of nurse anesthetists do not have bachelor's degrees, less than a quarter (22 percent) have a master's degree, and less than 1 percent have a Ph.D. In comparison, the writers note, all anesthesiologists have an undergraduate degree, 4 years of

medical school and specialty training in anesthesiology.

Response: We recognize that education and training requirements vary among the States. As previously noted, States are well skilled at deciding requirements related to health care professional licensing. Our change in the hospital rule deferring to State oversight is not an endorsement of one health professional over another. It is not a rule that defines medical or nursing standards of practice or educational preparation. The rule merely allows the authority (that is, States) whose traditional role it is to make such determinations (for example, which health care professional is trained to provide which health care services) to do so in the case of anesthesia administration.

Comment: There was some concern expressed that eliminating the Federal requirement for supervision would result in decreased physician involvement in the training of CRNAs. One commenter speculated that this provision would reduce the incentive for a physician to specialize in anesthesiology and physician-administered anesthesia would soon vanish.

Response: We disagree that eliminating the Federal supervision requirement will necessarily lead to physicians making decisions about practice specialties, other than anesthesiology. This rule change is not a judgment about the value or contribution of one health professional or another. We believe that with greater staffing flexibility, opportunities for collaboration between physicians and nurse anesthetists will increase based on individual patient needs, hospital characteristics, and an increasing ability to implement best practice protocols.

Comment: A few commenters thought that eliminating supervision by the anesthesiologist will limit the choice of anesthesia modalities and deprive patients of an appropriate anesthesia plan. These commenters stated that CRNAs are not trained in various types of nerve blocks and/or the use of certain devices. These additional skills are necessary to care for critically ill patients.

Response: This change in regulatory approach does not permit any licensed independent health care provider to practice beyond his or her licensed scope of practice. While we acknowledge there will continue to be medical interventions or treatments that fall under the practice authority of a medical licensee, these determinations are not, and never have been, made by Federal regulation, but by States, with

input from, and consultation with, licensed health professionals. Typically these decisions on practice issues fall to provider credentialing, licensing or certification authorities. All areas of health care are constantly faced with implementing new technologies, procedures, drugs, biologicals, or devices. As these new techniques become available we believe it is the responsibility of States, hospitals, and professional organizations to implement standards for training and assuring practice competency. In addition, we have no evidence to indicate that eliminating the Federal supervision requirement for CRNAs will limit the choice of anesthetic modalities or deprive patients of appropriate anesthesia plans.

Comment: There were a few comments stating that the evolution of non-physician practitioners is expanding through the use of well-trained and very capable professionals. Advanced practice nurses represent part of the movement to broaden access, increase efficiency and maintain health care quality. One commenter applauded our efforts to eliminate restrictions preventing full utilization of these highly trained and qualified health professionals.

Others wrote in with concerns that this rule was opening the door to allowing other independent health professionals to engage in unsupervised practice in hospitals and through other providers regulated by us. Some of these commenters pointed to increasing activity at the State level to expand scope-of-practice laws for nonphysicians. Examples, such as psychologists seeking prescribing authority and complementary and alternative medicine practitioners lobbying to expand their professional practice rights, have been used to argue that lesser-trained professionals are attempting to practice medicine without the appropriate training or supervision. They point out that these are more examples of loosening regulatory safeguards over the practice of medicine and patient care.

Response: States have an excellent track record of protecting patient health through their own regulations. We respect State control and oversight of health professionals by deferring to State licensing laws to regulate professional practice. We have determined that there is no need for continuing Federal preemption of State laws by maintaining a requirement for physician supervision of CRNAs as a special case. There is no evidence that States are any less concerned with ensuring safety and quality than the

Federal government, especially when it comes to the health and safety of their citizens. In fact, our evidence-based, outcome-oriented standards establish a shared commitment between us, the States, and Medicare providers to ensure safe, quality anesthesia administration. States have a good track record in determining best practices. In fact, it is at the State level where most direct input by health professionals into scope-of-practice licensing laws takes place.

Additionally, we believe that independently licensed health professionals have served a valuable role in expanding access to, and maintaining quality in, many health services. The change in the Federal requirement for physician supervision is not an endorsement of any health profession, model of care delivery, or promotion of a specific standard of care. It is a change in approach to regulatory oversight that recognizes the worth of State control in meeting regional/local needs.

Operating Surgeon Providing Physician Oversight

Previous regulation required physician supervision by either an anesthesiologist or the operating surgeon. We received many comments from surgeons asking about the surgeon's liability as well as questions about who would be considered in charge of the patient's care.

Comment: One surgeon noted that he is dependent on the anesthesiologist as a consultant to provide care and recommendations concerning his patient. Other surgeons did not want responsibility for the anesthesia care of their patients when they were not trained in anesthesia. One commenter stated "surgical residency programs have intensified training in surgical technical skills, and decreased emphasis on anesthesiology training, leaving such matters to the consultant in Anesthesiology. As a result, [the surgeon's] ability to supervise the CRNA has declined." This commenter asserted this should encourage us to require CRNA supervision by an anesthesiologist only. One anesthesiologist asked whether he would be responsible for anesthesia management done prior to his consultation.

Response: This final rule does not require supervision, direction, or oversight of any independently licensed practitioner administering anesthesia by the operating surgeon. The surgeon would still be able to involve an anesthesiologist as a consultant or in any other capacity. This rule does

nothing to restrict that relationship. CRNAs, as well as anesthesiologists, are accountable for their own practices, the care they deliver, patient outcomes, as well as insurance liability coverage.

Comment: A few commenters stated there will be increasing pressure on surgeons, from hospitals, CAHs, and ASCs, to eliminate the anesthesiologist. Another commenter wrote that he believes if we allowed this change, it would not be long before private insurers would refuse to pay physicians no matter how sick the patient or complex the procedure.

Response: This rule governs participation requirements for hospitals, CAH, and ASCs participating in the Medicare program. It does not eliminate, restrict, or in any way limit the practice of any practitioner. In addition, an insurance company cannot establish health professional practice rules that are in conflict with State licensing laws.

Comment: We received several comments asserting the physician supervision requirement was responsible for surgeons choosing not to practice in some settings because they do not want the liability associated with the supervision responsibility. One commenter noted that one possible result of lifting the Federal supervision requirement is that more surgeons may be willing to practice in geographical areas they previously would have avoided partially because they did not want to be responsible for supervising the CRNA. Some believed the rule change will alleviate fears of surgeons who were concerned about taking on increased legal liability. Others noted that removing the supervision requirement afforded greater flexibility for surgeons and hospitals to choose their anesthesia providers without fear of increased liability.

Response: The rule makes no legal change in the scope of malpractice liability, traditionally a State issue. Our rule, permitting any State licensed health professional permitted by the State to administer anesthesia would not definitively affect any provider or professional the same way in all States. Because both scope-of-practice and malpractice liability differs from state to state, as a general matter, any professional who has contact with the patient could conceivably be held liable for personal injury, depending on the facts and circumstances of the case and on the State's laws. This issue is not the subject of this rulemaking.

Rural Issues

Comment: We had many comments on this provision relative to the practice of nurse anesthetists in rural areas. Even

many physicians supported the changed supervision requirement in rural areas where access to anesthesiologists is limited. Some comments from surgeons practicing in small communities noted they have worked solely with CRNAs for all procedures, and they never felt they had a need for any additional supervision, regardless of the medical situation. They further point out that without nurse anesthetists willing to practice in medically underserved areas, no one would be available to administer anesthesia.

However, other physician commenters noted that under current regulation, even without a supervising anesthesiologist, the operating surgeon provides supervision to the nurse anesthetist. One commenter noted, "the administration of anesthetics by nurse anesthetists in rural communities of this country is a condition of necessity, not design, since these areas are generally underserved by physicians." The commenter disagrees with proposing a national standard based on these criteria.

Response: The intent of this rule is not to limit or prohibit any anesthesia care model. We are changing a thirty year old policy to more accurately reflect demands of current practice, variations in hospital, CAH or ASC, patient characteristics, resource management, technology, and ever-increasing medical knowledge. We concur with the experience of the commenters who state that nurse anesthetists have increased access to anesthesia care, and thereby, access to medical and surgical procedures that would likely be unavailable if not for a practitioner qualified to administer anesthesia. We disagree, however, that the new rule, by itself, will guarantee an adequate supply of CRNAs in rural settings. A patient population's medical or surgical needs; hospital, CAH, or ASC characteristics; State practice laws, etc. are all factors contributing to decisions of CRNAs about where to practice. These variables exist in rural as well as other geographic areas.

Comment: A few commenters believed we were erroneous in our assumption that allowing independent practice of CRNAs would increase access to needed medical procedures in rural areas. One commenter asserted we were wrong in our assumption that there is a problem of access to care in rural areas. CRNA commenters noted that CRNAs administer anesthesia unsupervised by an anesthesiologist in approximately 70 percent of rural hospitals within the United States, providing a full range of anesthetic

services (for example, surgical, obstetrical, and trauma stabilization).

Response: Without CRNA availability in certain areas there would be limits on the types of surgical interventions or procedures that could be performed in those areas, because no anesthesia professionals other than CRNAs would be available.

Comment: Several people asked that we create a rural carve-out for CRNA independent practice. Some of these commenters agreed with keeping the requirement for operating physician supervision, while others supported full independent practice. Still others, even though in agreement with a rural carve-out, wanted us to create a requirement for supervision by an anesthesiologist wherever there were no shortages of this physician specialty. Additionally, these commenters wanted assurance that patient care outcomes would continue to be monitored so that all patients would be receiving the care they deserve.

Response: The purpose of the change in the requirement is not simply to respond to the needs of physician shortage areas. We gave full consideration to this option but decided that the importance of increased flexibility, decreased burden, and broadened implementation of best practice protocols were important for hospitals in all geographic settings. We believe there is no reason for an across-the-board Federal requirement that could potentially limit development of new practice models of anesthesia delivery, or interfere with progress in promoting practices that improve patient outcomes.

There are additional mechanisms in place to support monitoring of patient outcomes. There are other hospital standards and oversight activities that address how care is delivered and identify mechanisms hospitals must have in place to assure patients receive safe, quality care.

Comment: One commenter stated that by expanding CRNA independent practice outside of rural areas, increased competition would occur with anesthesiologists for jobs in better served areas and would result in CRNAs choosing not to locate in less desirable and under-served areas. This commenter supported a rural carve-out for fear that without such a carve-out, these underserved areas would again experience access problems. Another commenter mistakenly believed that requiring physician supervision would result in CRNAs working without payment, leading small community operating rooms to close.

Response: CRNAs are paid under the CRNA fee schedule. The CRNA may furnish the service under the "medical direction" of a physician, usually the anesthesiologist, or the CRNA may furnish the entire anesthesia service without medical direction, while still under the supervision of the operating surgeon. Payment rules for CRNAs, as well as for physician anesthesiologists, do not change as a result of this rule.

This issue of health professional shortage has always been present but there is no way to predict that this will be a definite outcome of the rule change. The Congress, the Department of Health and Human Services, and the States continue to address the issue of health professional shortages through a variety of mechanisms, including increasing educational grants and loans for those who choose to practice in designated critical shortage areas.

Pre- and Post-Anesthesia Evaluations

Comment: Several writers cited the importance of the pre-anesthesia evaluation as critical to prevention of complication during and after a procedure. Many of these commenters felt that only a physician with detailed knowledge of medicine has the ability to make a reasoned, informed judgment about the medical state of a patient. Other commenters noted that in addition to the pre-anesthetic evaluation, all peri-operative assessment and care requires physician oversight. One commenter pointed out that anesthesia complications might be a result of several factors, including inadequate pre-anesthetic preparation, severity of concurrent disease, inappropriate monitoring and lack of post-anesthetic follow-up care. Another commenter stated this process is more accurately described as "pre-procedure assessment", indicating the importance of thorough consideration of the patient's medical needs.

Response: We agree with commenters that a variety of factors and contributing variables influence surgical and anesthesia outcomes. Our literature review and analyses of comments confirms our conclusion that interactions among and between these variables are difficult to isolate in terms of their individual effects on outcomes. Education and training programs for CRNAs include pre- and post-anesthesia care. Pre- and post-anesthesia assessment and monitoring are scope-of-practice issues determined by each State as it considers education and training requirements for professional licensing.

We are sensitive to the debate between physician anesthesiologists and nurse anesthetists regarding what

constitutes the practice of medicine with regard to anesthesia administration. States have handled these issues through laws and health professional practice acts. Questions of who is properly trained to do a pre-anesthesia evaluation, care for a patient in recovery, order pain medication, or perform a procedure that results in conscious sedation of a patient, have all faced States when they adopted professional licensing laws. This rule change does not prohibit collaboration between medical professionals including surgeons, nurse anesthetists, and/or anesthesiologists in the total care and treatment of any patient in the hospital. As expanded scope-of-practice issues are debated at the State level, we expect continued involvement by medical and health professionals to ensure best practices and protocols are incorporated in final decisions about which professionals meet the required training and education to perform any particular service.

Collaboration and Anesthesia Team Approach

Comment: Several commenters explained that this rule would not significantly change the manner in which CRNAs currently work. One commenter noted that "anesthesia always has been and always will be given only as an adjunct to a surgical or diagnostic procedure. Collaboration must occur with the primary physician no matter if the anesthesia is provided by a physician anesthesiologist or a nurse anesthetist." Other commenters reaffirmed this by pointing out that collaboration is intrinsic to the practice of anesthesia administration, and therefore an explicit requirement of supervision is at best unnecessary. Others brought to our attention that State laws that require supervision vary in their definitions and in many cases define supervision as collaboration rather than direction.

Several anesthesiologists commented in support of the collaborative, team approach to anesthesia delivery. Commenters stressed the valuable and knowledgeable assets CRNAs are to the anesthesia team. These commenters expressed some concern that the rule will destroy the longstanding concept of the anesthesia care team, making it less likely hospitals will take advantage of the skills of the nurse anesthetist and the medical training of the anesthesiologist.

Response: As we have said, this rule makes no judgment in support of one model of care over another. In addition, the rule does not prohibit collaboration or teamwork during anesthesia

administration. We believe the rule will promote best practices and encourage professional collaboration, in an effort to improve anesthesia care delivery and patient outcomes. We are pleased with the comments in recognition of the valuable contribution made by both professionals to the care of patients during anesthesia administration.

Comment: One commenter wrote that in most settings patient care is a team effort, and the current supervision requirement encourages polarization rather than collaboration. This commenter noted that when CRNAs have problems or questions about patient care they seek consultation with colleagues. Other commenters stated that the removal of the requirement provides surgeons, medical physicians, and others who perform diagnostic or surgical procedures freedom to collaborate or choose the anesthesia provider best suited to the procedure and the patient's needs. Additionally, many who supported the change in the rule believe that only a few CRNAs in certain circumstances would want to practice without supervision. They felt that both nurses and anesthesiologists preferred a team model of practice.

Two commenters stated that dentists, some physicians, and podiatrists work in settings where collaboration with an independent nurse anesthetist better suits the needs of the patient. They particularly noted the practice by nurse anesthetists of staying with patients for the entire duration of the procedure and through discharge from surgery as being helpful.

Similarly, we had several physicians state that the average healthy person can be safely managed by a CRNA. However, they contend a person with multiple medical problems or those undergoing complex or high-risk surgery should have a physician evaluation and medical direction during his or her care. The commenters believed that with this type of distinction in care, both parties would work together to deliver high quality anesthesia.

Response: One of the limits to requiring an overarching, across the board Federal requirement for supervision is the problem it creates for providers to tailor care to the needs of patients. These comments reaffirm what we have previously noted about the wide variability in patient presentations (for example, medical factors, type and nature of procedure, age, health, etc.) and how these variables influence clinical decisions about anesthesia administration. This rule change removes these unnecessary restrictions.

Cost to the Medicare Program

Comment: We received many comments on the financial motivations of various types of professionals for taking a position on one side of this issue or another. Many of the 20,000 comments accused one professional group or another of lacking concern for safety or adding additional burden to the health care delivery system for the sole purpose of financial gain or practice monopoly. We also received comments asserting that our motivation was to save money payable through the Medicare and Medicaid programs at the cost of quality anesthesia services. Those who support the change note that it removes a financial disincentive to use nurse anesthetists by no longer requiring payment to two professionals. They feel nurse anesthetist will be more efficient and expand a hospital's ability to provide services to more patients.

Many nurse anesthetists report having full responsibility for administering an anesthetic and caring for a patient while the anesthesiologist is somewhere else in the surgical area having no interaction with the patient. They note CRNAs are able to provide the same quality service at a lower cost, without the additional fee to an anesthesiologist for providing supervision. One commenter expressed support for the change as one that will greatly facilitate the use of cost-effective, outcome-based providers, noting "Unnecessarily mandated layers of supervision ultimately add cost to care, and yet have never documented any benefits." Many commenters wrote us with specific examples of how Medicare charges and costs would decrease as a result of the rule.

There was a common misunderstanding among many commenters that this change meant that Medicare patients would be forced to receive a lesser level of care because the rule changed the reimbursement for Medicare patients. One commenter asked, "Why would HCFA institute payment procedures that decrease the level of care provided to Medicare and Medicaid patients in the name of flexibility?" Another stated this rule proposes a double standard in that Medicare and Medicaid patients would not have the benefit of a physician's expertise to ensure their safety during critical peri-operative time.

Response: This rule does not change the payment policies for anesthesia services. Medicare payment rules remain the same. CFR section 415.110(a) requires that the anesthesiologist perform specific activities for each patient in order to be paid for providing

"medical direction." It must be emphasized that the "medical direction" rules are rules for payment of the physician's service under the physician fee schedule. The physician fee schedule payment per service is related to the amount of physician work associated with the service. Thus, the medical direction requirement must establish some level of physician work that is reasonable in relation to the allowance recognized for the service. The "supervision" of the CRNA by a physician, usually the operating surgeon, is not a separately payable service for the surgeon. The payment for this service is considered a part of the global surgical fee paid to the surgeon.

Because this rule does not affect payment, the determination about supervision is not specific to a Medicare beneficiary. These rules apply to all patients receiving anesthesia services in Medicare participating hospitals, CAHs, and ASCs, thus Medicare patients would not receive a different level of care from non-Medicare patients and therefore, does not mean different care for Medicare or Medicaid patients. The rule is specific to the provision of anesthesia services in a Medicare participating hospital, CAH, or ASC, and applies to all patients.

Comment: Several commenters who opposed this provision warned that costs to the Medicare program will increase as a result of this rule. Many believed that, although there will be no immediate effect since payment remains the same, costs would increase in the long term because of resulting anesthetic complications and malpractice. Others told us they believe anesthesiologist consultations will increase because some of these services are included in the anesthesia administration fee but as consultants, anesthesiologists would have to charge separately for these services.

Response: Neither costs to the Medicare program nor payment to different professionals was part of the decision to change the hospital CoP for anesthesia services. The fears of long term negative outcomes, increasing medical complications and higher malpractice insurance premiums, related to professional type, are unwarranted, based on our review of the literature. This rule will not prohibit consultation, physician supervision, or anesthesiologist administration of anesthesia where State and/or hospital by-laws require it. Whether payment can be made for consultations will be determined by the usual physician coverage and payment rules.

General

Comment: We received many anecdotal comments from beneficiaries, describing both positive and negative experiences during anesthesia, such as, the importance of a caring, well-trained professional who gives the needed patient attention, and answers the patient's questions. Rarely did the comments identify the professional by credentials.

Response: These reports are important in that they confirm our commitment to patient-centered, outcome-oriented approaches to regulating Medicare participating providers.

Comment: Several certified anesthesiology assistants (AAs) expressed concerns about how the rule might affect their practice. Since the rule allows anesthesia to be administered only by a person licensed by the State to do so, they question whether this requirement would prohibit their practice. Some of the AAs recommended that we omit the term licensed and allow States to determine whether licensure is required at all to practice anesthesia.

Response: We do not agree with the comments that no State licensure should be required for anesthesia health professional practice. As noted, this rule defers to State scope-of-practice laws which identify health professionals that are allowed to administer anesthesia. Under this rule, AAs would be allowed to practice within their scope-of-practice specified by State law.

Comment: One commenter recommended that we require a CRNA to disclose that a nurse, not a doctor, would be providing anesthesia care and that if the patient desired to choose another provider his or her request would be honored. Other commenters stated that this rule is being promulgated without adequate input from patient advocate groups and without regard to how it might affect patient care. They believe that this rule serves special interests and that patient interests have not been adequately considered.

Response: The request for an anesthesia provider is usually made by the surgeon or physician in charge of the patient's care. We believe the flexibility allowed through this rule change will enable physicians to make the best and most suitable choice for their patient's characteristics, medical and anesthesia needs. Patients are always free to ask about the qualifications of any practitioner providing care, including doctors, nurses, therapists, surgeons, or anesthesiologists.

We received comments regarding this proposal from patient advocates and individual Medicare and Medicaid beneficiaries as well as providers on both sides of the issue. We agree that safety and quality patient outcomes should be the principal consideration in regulating providers. It is exactly this focus which has led to the regulatory change in supervision of CRNAs.

Comment: Several commenters pointed to other ways in which the Federal government supported nurse anesthetists, citing, as examples, Federal funds under Title VIII of the Public Health Service Act and Medicare Education Funds. One commenter wrote that nurse anesthetists received approximately \$2.7 million dollars per year for student trainees, faculty fellowships, and new program startup money.

Response: As previously noted, this rule is not intended to endorse one health care professional over another. It is intended to recognize the value in flexibility for providers when making decisions about how to best manage resources to ensure access to quality health services.

Comment: We received a few comments from nurse anesthetists who believed that implementation of this rule would be easy in those parts of the country where CRNAs have practiced and are treated with respect. Some of these commenters identified difficulty in achieving professional courtesy and referrals from doctors who did not recognize their skills and abilities.

Response: To the extent that this rule provides opportunity for greater flexibility for providers and increased access to quality health care for patients, we hope that this will occur. It is not our goal in this rule to prescribe, or to limit, which health care professionals may collaborate, supervise or work independently. We do, however, hope to decrease barriers to access, increase efficiency, and encourage improved models of safe anesthesia delivery. We believe that is best accomplished by sharing the responsibility with States and providers.

III. Provisions of the Final Regulations

We are amending § 482.52(a)(4) of the current hospital CoPs and § 485.639(c)(1)(v) of the current critical access hospitals CoPs, to codify requirements for who may administer anesthesia under Subpart D—Standard: Anesthesia Services. This change is also reflected in a conforming amendment to the ASC Conditions of coverage at § 416.42(b)(2). This final regulation eliminates a Federal requirement for physician supervision and defers to

States the determination of which licensed practitioners are allowed to administer anesthesia.

IV. Collection of Information Requirements

This document does not impose information collection and record keeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

V. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more annually). This rule is not considered to have a significant economic impact on hospitals and, therefore, is not considered a major rule. There are no requirements for hospitals to initiate new processes of care, reporting, or to increase the amount of time spent on providing or documenting patient care services. This final rule will provide hospitals with more flexibility in how they provide quality anesthesia services, and encourage implementation of the best practice protocols.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 million or less annually. For purposes of the RFA, all non-profit hospitals, and other hospitals with revenues of \$5 million or less annually are considered to be small entities. Some critical access hospitals and some ASCs with revenues of \$5 million or less annually are also considered to be small entities. Individuals and States are not included in the definition of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of

a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million. This rule places no additional cost requirements for implementation on the governments mentioned. It will allow CRNAs to practice without physician supervision where State law permits or to be supervised by a physician where such oversight is required by State law. This change is consistent with our policy of respecting State control and oversight of health care professions by deferring to State licensing laws to regulate professional practice. Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule imposes no direct compliance costs on State or local governments.

B. Anticipated Effects

1. Medicare and Medicaid participating hospitals, CAHs, and Ambulatory Surgical Centers will defer to State licensing laws in determining which health professionals are permitted to administer anesthesia. In addition, these facilities are free to exercise stricter standards than required by State law.

2. First, it must be noted that this final rule does not change the Medicare payment policies for anesthesia services. There is an important payment distinction between the medical "direction" requirements and the physician "supervision" requirement. Payment made by Medicare on a fee schedule basis is not payment for "supervision" but rather payment for "direction" and the payment per service is related to the amount of physician work associated with the service.

Second, economic effects on individual health professionals as a result of this rule change will be influenced by other factors. Because the final rule defers to State licensing laws, the impact on either physician or CRNA income from billed services will be

determined by each States' laws. State laws vary widely in both the definition and degree of physician supervision and oversight required of CRNAs. In addition, some State laws leave the determination up to individual hospital, CAH, or ASC medical staff by-laws, resulting in a financial impact that is different depending on where the physician or CRNA provides the services. In any of these situations the potential impact might include an increase or decrease in billed services by CRNAs practicing alone, in billed services by physicians practicing alone, in billed services by physicians providing medical direction in collaboration with CRNAs, as well as the possibility of no change in billed services by either provider. In some of these cases, where there is decreased physician billing, there may be increased savings to third party payers.

Finally, the flexibility resulting from the rule change could provide increased access to services in some areas, and broaden opportunity for providers to implement professional standards of practice that improve quality and promote more efficacious models of care delivery.

3. This rule increases flexibility in the provision of anesthesia services for Medicare and Medicaid hospitals, CAHs, and ASCs. It removes the burden of implementing a Federal requirement for physician supervision of CRNAs in all cases. The rule change will allow hospitals, CAHs, and ASCs the flexibility, within the authority of State licensing laws, to implement best-practice protocols in providing anesthesia services most associated with positive patient outcomes. Moreover, hospitals are free to exercise stricter practice standards. As discussed in the preamble of the December 19, 1997 proposed rule, this provision does not lend itself to a quantitative impact estimate, and we do not anticipate a substantial economic impact either in costs or savings.

C. Conclusion

We are changing the current across-the-board Federal requirement for physician supervision of CRNAs to allow State control and oversight through professional licensing laws. This change applies to all Medicare and Medicaid participating hospitals, CAHs, and ASCs. Our decision to change the Federal requirement for supervision of CRNAs applicable in all situations is, in part, the result of our review of the scientific literature which shows no overarching need for a Federal regulation mandating any model of anesthesia practice, or limiting the

practice of any licensed professional. The clinical evidence indicates anesthesia outcomes have improved substantially in recent years such that anesthesia is a relatively safe procedure. Both our literature review and comment analysis made clear that there is such a range of variables and influences to be considered (for example, patient types, surgical procedure, and/or availability of technology) that a single Federal requirement applicable in all situations is unnecessary and may actually interfere with factors that promote quality patient outcomes.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

VI. Federalism

We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism. We have determined that it does significantly affect the rights, roles, and responsibilities of States. This final rule removes the Federal guideline that requires CRNAs to be supervised by a

physician and allows the laws of the States to determine which practitioners are permitted to administer anesthetics and the level of supervision required.

List of Subjects

42 CFR Part 416

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 42 CFR Chapter IV is amended as set forth below:

PART 416—AMBULATORY SURGICAL SERVICES

1. The authority citation for Part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Specific Conditions for Coverage

2. Section 416.42 is amended by revising paragraph (b) to read as follows:

§ 416.42 Condition for coverage—surgical services.

* * * * *

(b) *Standard: Administration of anesthesia.* Anesthesia must be administered by a licensed practitioner permitted by the State to administer anesthetics.

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

3. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), unless otherwise noted.

Subpart D—Optional Hospital Services

4. Section 482.52 is amended by revising paragraph (a) to read as follows:

§ 482.52 Condition of participation: anesthesia services.

* * * * *

(a) *Standard: Staffing.* The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered by only a licensed practitioner permitted by the State to administer anesthetics.

* * * * *



Thursday, October 23, 2003

CRNA

Certified Registered Nurse Anesthetists

American Association of Nurse Anesthetists

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[Table of Contents](#)

[CRNA Homepage](#)

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Quality of Care in Anesthesia

Section Two

Anesthesiologist Distortions Concerning Quality of Care

4. Silber Study in *Anesthesiology*

[Silber, JH, Kennedy, SK, Even-Shoshan, O, Chen, W, Koziol, LF, Showan, AM, Longnecker, DE. "Anesthesiologist Direction and Patient Outcomes." *Anesthesiology*. 2000; 93:152-63.]

In September 1998, anesthesiologists began publicizing a scientific abstract titled "Do Nurse Anesthetists Need Medical Direction by Anesthesiologists?" The abstract was published in *Anesthesiology* (1998; 89:A1184), the journal of the American Society of Anesthesiologists (ASA), and reported the findings of a study, conducted in Pennsylvania, which compared the outcomes of surgical patients whose anesthesia was directed by anesthesiologists with patients whose anesthesia was directed by other physicians, such as surgeons. The study came to be known as the "Pennsylvania study."

Nearly two years later, the Pennsylvania study was published in the July 2000 issue of *Anesthesiology* with the title, "Anesthesiologist Direction and Patient Outcomes." Reportedly, both the *Journal of the American Medical Association* and the *New England Journal of Medicine* declined to publish the Pennsylvania study, forcing the ASA to publish the study in its own journal if it wanted the study to be published at all. Given the ASA's political agenda and the composition of *Anesthesiology's* editorial board, which is exclusively comprised of more than 40 anesthesiologists, serious questions of objectivity can be raised.

Then, on January 18, 2001, the Health Care Financing Administration (HCFA, which became the Centers for Medicare & Medicaid Services, or CMS, in June 2001) published a 14-page anesthesia rule in the *Federal Register* (Vol. 66, No. 12, pp. 4674-87) that affirmed, in no uncertain terms, AANA's contention that the Pennsylvania study is not relevant to the issue of physician supervision of nurse anesthetists. (The January 18 rule was rescinded on November 13, 2001, with the publication of a new rule that allows state governors to write to CMS and opt out of the federal physician supervision requirement after meeting certain conditions. The January 18 rule's extensive comments supportive of nurse anesthetists and dismissing the relevancy of the Pennsylvania study to the supervision issue, however, have in no way been repudiated by CMS and still remain part of the public record.)

On its surface, the study suggests that patient outcomes are better when nurse anesthetists are directed by anesthesiologists. However, a closer examination clearly reveals that the study

- is not about anesthesia care provided by nurse anesthetists

- actually examines post-operative physician care.

A. Background

The study was conducted using data obtained from Health Care Financing Administration (HCFA) claims records. The study group consisted of 217,440 Medicare patients distributed across 245 hospitals in Pennsylvania who underwent general surgical or orthopedic procedures between 1991-94. Dr. Silber headed a research team that included three anesthesiologists.

B. Study Does Not "Compare Anesthesiologists Versus Nurse Anesthetists"

According to Dr. Longnecker, one of the anesthesiologist researchers: "The study ... does not explore the role of (nurse anesthetists) in anesthesia practice, nor does it compare anesthesiologists versus nurse anesthetists. Rather, it explores whether anesthesiologists provide value to the delivery of anesthesia care." (Source: Memorandum from Dr. Longnecker to Certified Registered Nurse Anesthetists in University of Pennsylvania Health System's Department of Anesthesia, October 5, 1998)

Why, then, was such a misleading title ("Do Nurse Anesthetists Need Medical Direction by Anesthesiologists?") chosen for the abstract? The answer: for political reasons. Consider these facts:

- The abstract was published in the midst of the controversy between anesthesiologists and nurse anesthetists over HCFA's proposal to remove the physician supervision requirement for nurse anesthetists in Medicare cases.
- The study was funded in part by a grant from the American Board of Anesthesiology, which is affiliated with the ASA. ASA vehemently opposes HCFA's proposal.

Why was the name of the abstract changed prior to publication of the paper in the July 2000 issue of *Anesthesiology*? Most likely for the following reasons:

- As Dr. Longnecker stated in his memorandum, the study was not intended to examine the question posed by the abstract's title.
- The study clearly could not and did not answer the question posed by the abstract's title.
- Pressure from AANA in the form of statements to the media and commentary published on the Internet forced the researchers and ASA to rename the paper for publication.

C. Problems with the Data

Careful examination of the "findings" reported in the paper reveal numerous problems.

Glaring Admissions. In the next to last paragraph of the paper, the researchers conclude that, "Future work will also be needed to determine whether the mortality differences in this report were caused by differences in the quality of direction among providers, the presence or absence of direction itself, or a combination of these effects." Boiled down, *this clearly is an admission by the researchers that the study does not, in fact, prove anything about the effect -- positive or negative -- of anesthesiologist involvement in a patient's overall care, let alone the patient's anesthesia care!*

This statement appears in a section titled "Discussion," which is devoted primarily to explaining away the limitations of the billing data used (HCFA's claims records comprise a retrospective database intended for billing purposes, not quality measurement) and the myriad adjustments for variables which the data required the researchers to make. According to the researchers, among other adjustments were those made for severity of illness and the effect of hospital characteristics.

The researchers, however, admit the following:

- "The accuracy of our definitions for anesthesiologist direction (or no direction) is only as reliable as the bills (or lack of bills) submitted by the caregivers."
- "We cannot rule out the possibility that unobserved factors leading to undirected cases were associated with poor hospital support for the undirected anesthetist and patient."
- "...if anesthesiologists had a tendency not to submit bills for patients who died within 30 days of admission, our results could be skewed in favor of directed cases."

These admissions by the researchers seriously limit the application of the data. They are also proof that ASA's use of data from this study, in advertising campaigns and lobbying efforts to discredit nurse anesthetists and frighten seniors, has been opportunistic, misleading, and ethically reprehensible at best.

Time Frame. Nurse anesthetists do not diagnose or treat nonanesthesia postoperative complications -- they administer anesthesia. According to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), anesthesia mishaps usually occur within 48 hours of surgery. The study, however, evaluated death, complication, and failure to rescue rates within 30 days of admission, encompassing not only the time period of the actual surgical procedures, but also a substantial period of postoperative care as well. Therefore, it is impossible to know from the data how many or what percentages of deaths, complications, and failures to rescue occurred within that 48-hour window and were directly attributable to anesthesia care. However, if one considered the study's sample size (217,440) in relation to the widely accepted anesthesia mortality rate of one death in approximately 240,000 anesthetics given, which is recognized by ASA, AANA and cited in the Institute of Medicine report, *To Err is Human: Building a Safer Health System* (Kohn LT, Corrigan JM, Donaldson MS. Washington, DC: National Academy Press. 1999.), logic would dictate that less than a single individual in the entire database is likely to have died as the direct result of an anesthesia mishap!

What that leaves is this: *Based on the 30-day time frame, it is clear that the study actually evaluates postoperative physician care, not anesthesia care.*

Death Rates. The Pennsylvania study cites death rates that were many times more than the anesthesia-related death rates commonly reported in recent years, again leading one to conclude that the increase was almost certainly due to nonanesthesia factors.

In a June 2000 press release about the Pennsylvania study, the ASA stated "that patient safety has greatly improved from one [death] in 10,000 anesthetics to one in 250,000 anesthetics." (This amounts to four deaths in one million.) In the same press release, the ASA stated that, "Dr. Silber's

findings show that for every 10,000 patients who had surgery, there were 25 more deaths if an anesthesiologist did not direct the anesthesia care." Through a complex series of calculations, the difference translates to 8,000 deaths in one million. Thus, the difference in mortality rates that the ASA cited is **2,000 times** the mortality rate ever attributed (including by the ASA) in the last decade to the administration of anesthesia. To attribute a difference of this magnitude solely to the supervision of CRNAs is ridiculous. In actuality, the large differences in mortality and failure-to-rescue are due to differences unrelated to the administration of anesthesia and outside the scope of practice of CRNAs, whether unsupervised, supervised by anesthesiologists, or supervised by other physicians.

Further, it has been noted by Dr. Michael Pine, a board-certified cardiologist widely recognized for his expertise in analyzing clinical data to evaluate healthcare outcomes, that after adjusting the death rates for case mix and severity, *the patients whose nurse anesthetists were supervised by nonanesthesiologist physicians were about 15% more severely ill than the patients whose nurse anesthetists were supervised by anesthesiologists.* The paper provides no information to explain why the anesthesiologist-supervised cases involved less severely ill patients.

Dr. Pine's analysis of the study also reveals the following:

1. 7,665 patients (3.5%) died within 30 days of surgery.
2. Although the study found 258 more deaths of patients who may not have had an anesthesiologist involved in their case, the researchers' adjustments for differences among patients and institutions reduced the number by 78% (to 58 deaths).
3. The 58 "excess" deaths could be due to numerous, equally plausible factors, for example:
 - A. Faulty design of the study
 - B. Inaccurate or incomplete billing data (e.g., most of the 23,010 "undirected" cases used had no bill for anesthesia care)
 - C. Unrecognized differences among patients (e.g., medical information on patients' bills was insufficient to permit complete adjustment for their initial risks)
 - D. Unrecognized differences in institutional support (e.g., information about hospital characteristics was inadequate to permit full assessment)
 - E. Medical care unrelated to anesthesia administration (e.g., post-operative medical care provided by anesthesiologists or by other medical specialists who are more likely to be at hospitals in communities where anesthesiologists are plentiful)

The end result is a statistically insignificant difference in negative out- comes

between anesthesiologist-directed and nonanesthesiologist-directed cases.

Complication Rates. After adjusting for case mix and severity, *the study found no statistically significant difference in complication rates when nurse anesthetists were supervised by anesthesiologists or other physicians.* Dr. Pine noted that poor anesthesia care is far more likely to result in significant increases in complication rates than in significant increases in death rates. Therefore, Dr. Pine concluded that this finding strongly suggests that medical direction by anesthesiologists did not improve anesthesia outcomes.

Failure to Rescue. For the most part, failure to rescue occurs when a physician is unable to save a patient who develops nonanesthesia complications following surgery. Therefore, it is not a relevant measure of the quality of anesthesia care provided by nurse anesthetists. It is a relevant measure of postoperative physician care, however.

Patients Involved in More than One Procedure. For reasons not explained in the abstract, patients involved in more than one procedure were assigned to the nonanesthesiologist physician group if for any of the procedures the nurse anesthetist was supervised by a physician other than an anesthesiologist. It is impossible to measure the impact of this decision by the researchers on the death, complication, and failure to rescue rates presented in the abstract.

To emphasize the importance of this, consider the following hypothetical scenario: A patient is admitted for hip replacement surgery. A nurse anesthetist, supervised by the surgeon, provides the anesthesia. The surgery is completed successfully. Three days later the patient suffers a heart attack while still in the hospital and is rushed into surgery. This time the nurse anesthetist is supervised by an anesthesiologist. An hour after surgery, and for reasons unrelated to the anesthesia care, the patient dies in recovery. According to the researchers, a case such as this would have been assigned to the nonanesthesiologist group!

Patients Who Were Not Billed for Anesthesia Services. As noted in the discussion on death rates, most of the "undirected" cases had no bill for anesthesia care. The actual figure is 14,137 patients, or 61% of the 23,010 patients defined as undirected. The researchers' flimsy rationale for lumping all nonbilled cases in the undirected category is as follows: "The 'no-bill' cases were defined as undirected because *there was no evidence of anesthesiologist direction, despite a strong financial incentive for an anesthesiologist to bill Medicare if a billable service had been performed*" (emphasis added). Of course, one might ask how many of those cases were not billed because an anesthesiologist had a bad patient outcome.

Referenced Studies. The researchers claim that their research "results were consistent with other large studies of anesthesia outcomes." Interestingly, the two studies cited were by Bechtoldt and Forrest. As indicated below, neither of these studies agrees with the conclusions reached by Dr. Silber and his team of researchers on the Pennsylvania study:

- Bechtoldt reported that the Anesthesia Study Committee (ASC) of the North Carolina Medical Society "...found that the incidence among the three major groups (the CRNA, the anesthesiologist, and the combination of the CRNA and anesthesiologist) to be rather similar. Although the CRNA working alone accounted for about half of the

anesthetic-related deaths, the CRNA working alone also accounted for about half of the anesthetics administered."

- After applying statistical tests to the results of research conducted by the Stanford Center for Health Care Research, Forrest stated: "Thus, using conservative statistical methods, we concluded that there were no significant differences in the outcomes between the two groups of hospitals defined by type of anesthesia provider. Different methods of defining outcome changed the direction of differences for two weighted morbidity measures."

Further supporting the argument that other studies do not agree with the purported findings of Silber and his fellow researchers is the following objective, third-party opinion offered by HCFA/CMS in the *Federal Register* on January 18, 2001: Our decision to change the Federal requirement for supervision of CRNAs applicable in all situations is, in part, the result of our review of the scientific literature which shows no overarching need for a Federal regulation mandating any model of anesthesia practice, or limiting the practice of any licensed professional." (p. 4685-4686)

D. HCFA/CMS Affirms that Study Not About CRNA Practice

In the anesthesia rule published in the January 18, 2001, *Federal Register* by HCFA/CMS, the administration dismissed all claims by ASA and the Pennsylvania study research team that the study examined CRNA practice and was relevant to the supervision issue. HCFA/CMS stated the following:

- "We have also reviewed a more recently published article by Dr. Silber (July 2000) and colleagues from the University of Pennsylvania. This article also is not relevant to the policy determination at hand because it did not study CRNA practice with and without physician supervision, again the issue of this rule. Moreover, it does not present evidence of any inadequacy of State oversight of health professional practice laws, and does not provide sound and compelling evidence to maintain the current Federal preemption of State law." (p. 4677)
- "One cannot use this analysis to make conclusions about CRNA performance with or without physician supervision." (p. 4677)
- "Even if the recent Silber study did not have methodological problems, we disagree with its apparent policy conclusion that an anesthesiologist should be involved in every case, either personally performing anesthesia or providing medical direction of CRNAs." (p. 4677)

Although the January 18 rule was rescinded on November 13, 2001, with the publication of a new rule that allows state governors to write to CMS and opt out of the federal physician supervision requirement after meeting certain conditions, the January rule's extensive comments supportive of nurse anesthetists and dismissing the relevancy of the Pennsylvania study to the supervision issue have in no way been repudiated by CMS and still remain part of the public record.

E. Conclusions

The following conclusions can be drawn from a careful examination of the study "Anesthesiologist Direction and Patient Outcomes":

- The study described has nothing to do with the quality of care provided by nurse anesthetists.

- The study examines postoperative physician care, not anesthesia care.
- The researchers so much as admit that the study does not prove anything with regard to the effect of anesthesiologist involvement in patient care.
- The timing of the publication in the ASA's own journal was politically motivated.
- HCFA/CMS finds no credence in ASA and Dr. Silber's assertions regarding the results of the Pennsylvania study.

On to Summary

Back to New England Journal of Medicine Articles



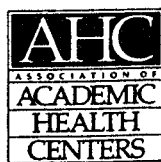
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Power, Politics, and Policy

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Editors

*with introductory papers by
economist Uwe E. Reinhardt
and
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Contents

Preface	iii
Contributors	xi

Setting the Stage

The Economic and Moral Case for Letting the Market Determine the Health Workforce	3
<i>Uwe E. Reinhardt</i>	

Ethical Responsibilities of Academic Health Centers in the New Health Care Market	15
<i>Dan W. Brock</i>	

Federal Roles

The Political History of Health Workforce Policy	31
<i>Daniel M. Fox</i>	

Federal Regulation and Market Forces in Physician Workforce Management	47
<i>David A. Kindig</i>	

Health Workforce Policy Lessons From Britain	57
<i>Michael Ashley-Miller</i>	

Physician Workforce Policy in Canada	69
<i>Harvey Barkun</i>	

State Roles

The Political Context of State Regulation of the Health Professions	81
<i>Carol S. Weissert</i>	

Health Care Market Reforms and Their
Effect on Health Professions Regulation 93
*Edward H. O'Neil, Leonard Finocchio, and
Catherine Dower*

Developing Rational Health
Professions Licensure 107
Judy C. Kany

The Virginia Generalist Initiative
State Regulation of Physician Supply 121
R. Michael Morse

The View From the Legislature 127
Stephen A. Horan

The Effect on Medical Education 133
C. Donald Combs

Roles of the Market

The Nursing Workforce
in a Time of Change 141
Karl D. Yordy

Deploying Primary Care Personnel in Managed
Care Plans: More Art Than Science 153
Bernard J. Mansheim

A Staff-Model HMO Perspective
on Health Care Staffing 159
Kathleen Cooney

The Corporatization of Health Care: Effect
on Accreditation and Academic Integrity 167
C. Edwin Webb

A New Health Professions Curriculum
for a New Delivery System 175
Richard J. Davidson

Roles of the Health Professions

The Evolution of New Health Professions:
A History of Physician Assistants 189
James F. Cawley

The Interplay Between the Supply of Physicians
and Advanced Practice Nurses 209
Geraldine D. Bednash

Health Professions Substitution:
A Case Study of Anesthesia 219
Jerry Cromwell

Roles of Educational Institutions

New Health Workforce Responsibilities
and Dilemmas 231
Neal A. Vanselow

Responses to Neal A. Vanselow

Special Issues for Osteopathic Medicine 243
David G. Marker

The Challenge of Primary Care
for Academic Health Centers 247
Vincent A. Fulginiti

Measuring the Costs of Primary Care
Medical Education 253
Ruth S. Hanft

Health Workforce Policy and Planning
in a University: A New Approach 263
Leonard L. Ross

Forecasting

Health Workforce Modeling: Lessons
From Dentistry 277

Eli Capilouto and Robert Ohsfeldt

Extrapolating HMO Staffing
to the Population at Large 311

*Jonathan P. Weiner, Christopher J. McLaughlin, and
Sandy Gamliel*

Changing Values, Changing Policies

A Framework for Improving the Health
Workforce Policy Process 329

Marian Osterweis and Christopher J. McLaughlin

Health Professions Substitution

A Case Study of Anesthesia

JERRY CROMWELL

Substitution in health professions is an extremely important issue, particularly in today's practice environment. For a long time, we in the health economics profession specifically, and in the nation generally, have been looking for the Holy Grail—the elusive optimal provider mix. By optimal, I mean the most cost-effective mix of provider inputs, not simply the lowest cost. As an economist, I see a number of market failures that lead to a less than optimal provider mix. These market failures can be attributed to three general causes.

The first cause is insurance. When patients are not paying the full cost of their care, they are not as price-sensitive to cost, and hence to the input mix, as they might otherwise be.

Second, is the tremendous amount of ignorance on the part of both patients and providers of the kinds of services the patients actually need and the most cost-effective provider input mix needed to provide these services. Much of the health services research in the Federal government today is devoted to research in this area.

Third, is the interesting relationship that has developed between doctors and the hospitals where they practice. Hospitals historically have been doctors' workshops where they can use all the services of the hospital basically for free. This situation has resulted in less cost-effective management of hospital resources than otherwise might be possible.

Identifying Possibilities for Physician Substitution

Research on physician substitution has been going on since the advent of Medicare and Medicaid. In some areas, extensive substitution is already going on. We know that nurses provide a significant amount of substitution

for physicians in both the office and the hospital. They are midwives, assistants at surgery, and physician extenders. An extensive number of allied health professions also contribute to substitution.

The Federal government has played a role in determining the workforce mix, primarily in support of physician and allied health education. They have also conducted a number of studies of workforce trends and productivity, research that was more prevalent in the 1970s than thereafter. But the area in which the government has affected the workforce mix most profoundly has been in its service reimbursement policies.

The private sector's role in workforce management has been relatively minor until recently. Except for the large health maintenance organizations like Kaiser Permanente, there hasn't been too much consideration in the private sector of what constitutes an optimal provider input mix. Currently, the private sector, through managed care, is starting to worry about that mix.

Anesthesia Substitution

Anesthesia is an excellent laboratory for studying substitution. Anesthesia is a traditional nursing function that has been replaced, in fair part, by physicians over the past 20 to 25 years. There are significant cost implications to the wrong provider input mix in anesthesia, simply because of the tremendous differences in cost between nurse and physician providers (Rosenbach and Cromwell 1988). Anesthesia, therefore, provides an excellent example of what can go wrong with the workforce mix when you pay for inputs (i.e., types of providers) rather than outputs (i.e., the services delivered). Federal and third-party reimbursement have paid for anesthesia inputs rather than outputs. This major flaw in the reimbursement system explains the inefficient mix we've developed in anesthesia (Cromwell and Rosenbach 1988).

There are three basic models of anesthesia practice.

1. In the solo anesthesiologist model, the physician, practicing alone, handles all the cases in the hospital. In some instances around the country, solo nurse anesthetists practice alone and handle all of the cases.
2. In the second model, a hospital has a mix of the two providers, yet each may be practicing solo on any one case depending on the case and the time of the day.
3. In the anesthesia team arrangement, a physician anesthesiologist (MDA) supervises a certified registered nurse anesthetist (CRNA).

Extent of MDA-CRNA Substitution

Significant regional differences in the mix of the two anesthesia providers leads me to believe that there are significant opportunities for provider mix improvement. In California, there are two anesthesiologists for every CRNA. In South Dakota, there are seven and a half CRNAs for every anesthesiologist (Rosenbach et al. 1988).

What do these two types of providers do in their delivery of anesthesia? The following data are based upon the federally funded Anesthesia Practice Survey, a 1986 survey of roughly 500 each of anesthesiologists and CRNAs randomly selected around the country (Rosenbach et al. 1988). To my knowledge, there is no more recent comprehensive random survey of anesthesia practice patterns.

CRNAs provide a substantial amount of anesthesia activities. They evaluate patient-risk factors in at least half (51 percent) of their cases; in more than half of their the cases (61 percent), they discuss the anesthesia plan with the patient or the family. In roughly half of their the cases (45 percent), they evaluate the patient in recovery. They administer regional anesthesia roughly a third (29 percent) of the time. They insert arterial lines about a third (36 percent) of the time, but they are much less involved in inserting other invasive monitoring devices such as central venous pressure lines and Swan-Ganz catheters. These data tell us that the CRNAs are actively involved in just about all of the major anesthesia activities.

When cases are stratified by anesthesia complexity and model of practice (e.g., solo CRNA, solo MDA), three conclusions are noteworthy, (Rosenbach et al. 1988; Rosenbach and Cromwell 1988). First, solo CRNAs are far more involved in vaginal deliveries than are anesthesiologists. Second, anesthesiologists are only slightly more likely to perform the more complex anesthesia procedures in the nation. And third, a significant percentage of solo anesthesiologists are doing simple anesthesia procedures (e.g., dilation and curettage, vaginal delivery, and hernia repair).

A favorite economic method of study is activity analysis. In the Anesthesia Practice Survey, respondents provided a daily log of roughly 4,000 operations. Figure 1 categorizes these operations in terms of percent of MDA time devoted to each case on the vertical axis; CRNA time is depicted on the horizontal axis. At the top of the vertical axis are about 1,200 cases in which the anesthesiologist was practicing alone. On the horizontal axis are about 700 cases in which the nurse anesthetist was practicing alone. The 45° line is the full-time equivalent (FTE) line, which is a one to one substitution of anesthesiologist time for CRNA time.

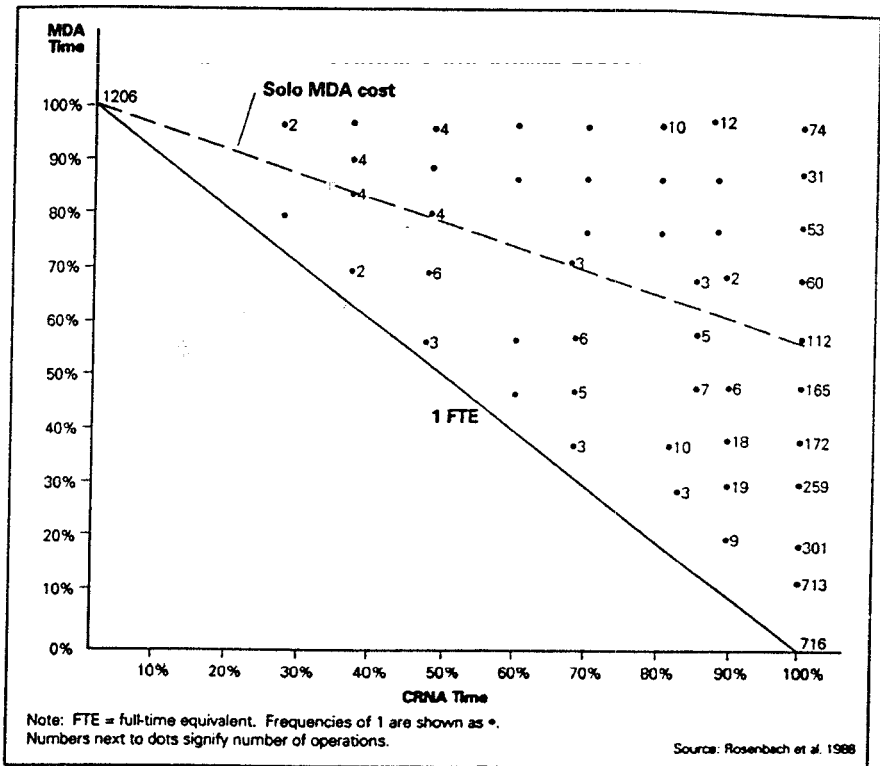


Figure 1. Percent CRNA-MDA Time (4,000 operations), 1986

All of the observations are either on these two corner points, the two solo points, or above the point where more than one FTE is on a case. All dots represent numbers of cases with more than one FTE practitioner on a case. The dashed cost line represents the solo MDA cost line. Given the relative cost difference of the two providers, the dashed line represents all of the combinations of the two providers that would be equivalent to the cost of an anesthesiologist practicing alone. Thus, all cases above the dashed line effectively cost more than an anesthesiologist practicing alone. A large proportion of cases are in the gap between the 45° FTE line and the solo MDA cost line at varying percentages of MDA-CRNA activity. The procedures that fall in the range above the MDA cost line are those in which managed care organizations, and every other payor, will seek cost-savings by changing the provider mix to get much below the MDA-cost line, and in some cases, particularly in simpler ones, to much below the MDA cost-line. It illustrates opportunities for potential professional arbitrage.

CRNA practice raises MDA productivity; it is the kind of situation that managed care organizations look at closely. The solo anesthesiologist sees an average of 3.7 patients per shift (Cromwell and Rosenbach 1990). Working in a team with a CRNA, the MDA sees 6.5 patients per shift, a 75 percent increase in the number of patients per shift (Cromwell and Rosenbach 1990). Even adjusting for the complexity of certain surgeries, there is a 63 percent greater increase in anesthesiologist productivity when the MDA works in a supervisory capacity. The anesthesiologist in a team works with a CRNA for the equivalent of more than 8 hours of CRNA time during the anesthesiologist's shift. Only about 60 percent of the procedures that the anesthesiologist does are concurrent. The other 40 percent of the time, the anesthesiologist is working on his or her own cases and is not directly supervising a CRNA. Thus there are still opportunities for additional productivity even in the team scenario.

Relative Cost of Each Provider

There have been tremendous increases in the nominal incomes of both MDAs and CRNAs. The average reported income for anesthesiologists increased roughly 80 percent during the ten-year period 1983 to 1993 (AMA 1994). The actual increase in income for CRNAs was 100 percent in this period (AANA 1988; AANA 1994).

Comparing hourly incomes, the more relevant marginal measure for economic analysis, we see some compression in the relative cost difference in ten years. In 1983, anesthesiologists cost 2.2 times what a CRNA cost (\$51.84 per MDA hour, \$23.80 per CRNA hour). The MDA cost difference has compressed somewhat to approximately 1.8 times that of a CRNA (\$87.44 to \$49.20). The compression is due to the relatively large increase in CRNA salaries over the ten years. Nevertheless, managed care organizations and government payors may take advantage of the resulting arbitrage gap.

Forecasting Shortfalls in CRNAs

In 1980, there were approximately 17,500 CRNAs and 13,000 MDAs in practice in the United States. There was some increase from 1980 to 1985 in the number of full-time equivalent CRNAs practicing. From 1985 to 1992, the supply was effectively flat at approximately 20,000 (Cromwell et al. 1991). Over that same period, there was a rapid growth in the number of anesthesiologists practicing in the United States. By the early 1990s, the number of full-time active CRNAs and MDAs was basically the same (ASA

1995; AANA 1995). Given the demonstrated opportunities for MDA-CRNA substitution, equal supplies of the two providers imply an increasingly non-cost-effective provider mix.

The main reason for the flattening in nurse anesthetist supply is the significant decline in the number of training programs. From 1981 to 1985, thirty-eight programs closed (AANA 1989). From 1986 to 1990, another twenty programs closed. During that same decade, from 1986 to 1990, the average number of graduates per year declined from almost 1,000 per year down to 633. A low point of about 575 graduates was reached in 1987. The situation has turned around in the 1990s. The number of CRNA programs has begun to rise again slowly, and the size of those programs have begun to grow again. In the period from 1990 to 1994, programs were averaging 866 graduates, and for 1996, the AANA is projecting well over 1,100 CRNA graduates (AANA 1995).

In a study for the Division of Nursing in the U.S. Health Resources and Services Administration, I analyzed the forecasted shortfall in CRNAs by the year 2000 under various low and high scenarios of CRNA supply and need (Cromwell et al. 1991).

Under any forecast, there is a significant CRNA shortfall, ranging from 6,852 to 9,816 FTEs. If one wants to move towards what is perceived to be a more economically efficient provider mix, then the shortfall of CRNAs doubles to about 18,000 to 21,000 FTEs by the year 2000. This forecasted decline in supply has concerned public policy makers as well as the private sector. Although it appears that educational institutions are responding to the shortfall, growth in CRNA supply is far below what is required to support widespread adoption of the team concept.

Factors Driving Future Demand

Some of the factors driving future demand for anesthesia providers include

- Health Care Financing Administration (HCFA) payment reductions for anesthesiologists have been going on for six to eight years in various forms. These reductions are forcing more supervision on the part of anesthesiologists so they can meet any target incomes they may have.
- There is a strong movement toward competitive bidding or bundled payment for inpatient services. In the HCFA heart bypass demonstration, the government pays a single rate for bypass surgery to seven hospitals in the country. This single rate covers both the hospital component as well as the surgeon, the anesthesiologist, and all the consult-

ing physicians in the hospital. The hospital and the physicians divide up the basic payment anyway they like. HCFA is expanding the demonstration by going into other heart procedures and are also expanding it to orthopedics. This payment method is having profound effects on the way that anesthesia is practiced in the hospitals. (Of course, private insurers have picked up on the government's lead in this bundled payment arena and negotiated bundled payment arrangements throughout the country.)

- Medicare has debated the adoption of physician diagnostic-related groups (DRG) for at least ten years. HCFA is serious about bringing inpatient physicians under the same Medicare payment incentives that the hospitals have been under for the last ten years. HCFA is setting up a demonstration to test a medical staff DRG payment system where the medical staff, along with the hospital itself, will negotiate a bundled payment for DRGs in the hospital.
- There are Medicare and state reductions in teaching support.
- There has been an aggressive shift toward managed care.

California is a great laboratory for studying arbitrage potential between managed-care and private fee-for-service organizations. The Kaiser Permanente hospitals in southern California have about 0.4 anesthesiologists for every full-time CRNA. The ratio for the rest of California is 2.6 anesthesiologists for every CRNA (Rosenbach et al. 1988). Here is a phenomenal difference in the mix of the two inputs within the same state. If the entire state went the Kaiser way in terms of the mix of the two anesthesia provider inputs, jobs for anesthesiologists in California would decline by roughly 1,200; a similar increase in CRNA jobs in California would also occur.

Occupational Power Struggles

Anesthesiologists are responding to the growing threats to their profession, their incomes, and their practices by expanding practices in order to increase their market power. They have lobbied hard against bundled payment in any kind of hospital arrangement and any kind of DRGs that would force the hospital to internalize its costs of providing anesthesia. They have also shifted strongly to solo practice so they can avoid reduced reimbursement due to concurrent care.

Shifting to solo practice requires limiting CRNA access to hospitals. Anesthesiologists have done this in two primary ways. They have limited CRNA teaching programs. (There were many complaints about anesthesi-

ologists training their competitors.) Then, anesthesiologists around the country presented the hospitals with a "them" or "us" ultimatum. A current lawsuit over CRNA dismissal in Minneapolis-St. Paul symbolizes this occupational warfare between the CRNAs and the anesthesiologists.

Hospitals will be inclined to favor the anesthesiologists over the CRNAs for the simple reason that the hospital right now is not paying for either provider; naturally, the hospital will select the anesthesiologist because of the greater training, and, prestige associated with a physician provider. It is not a cost-effective trend, but it's being forced on hospitals at this point.

Nurse anesthetists, in turn, have not been idle, but have mobilized impressive economic and political power. They've successfully lobbied Congress to not be bundled in the Medicare Part A DRG payment but, instead, to be treated separately and independently. They've lobbied Congress successfully for Medicare direct billing. They've lobbied Congress, HCFA, and the Physician Payment Review Commission for equal reimbursement—not only the ability to bill patients directly, but as independent providers billing at rates roughly comparable to anesthesiologists. They've sued hospitals that have dismissed them. They've also supported the trend toward physician DRGs, that is, internalizing in the hospital the relative costliness of the two providers in order to force the institution to make more cost-effective decisions.

Implications For Training in Anesthesia

Let me summarize five facts that are pertinent to future training decisions in anesthesia. (The first three are also relevant to training in other physician specialties.)

1. Spending in health care will slow dramatically over the next ten years.
2. The government is going to cut back on its teaching support.
3. Meaningful managed care competitive bidding will come to dominate reimbursement over the next five to eight years. A lot of experiments in managed care that have not been effective in terms of cost control in the 1980s are pretty much being weeded out. We now have much more rigorous competitive bidding in managed care.
4. Nurse anesthetists can perform nearly all the anesthesia tasks with minimal supervision and are nearly perfect substitutes for anesthesiologists.
5. Nurse anesthetists are significantly less expensive than anesthesiologists.

From these five facts, I draw four conclusions.

1. CRNAs will be in greater demand over the next ten years, and in significantly greater demand depending on how fast and how hard the public and private payors push.
2. The demand for anesthesiologists will diminish, as already has happened in California and elsewhere.
3. Anesthesiologists are going to find their responsibilities shifting significantly away from hands-on anesthesia towards supervising, concentrating on complex cases and providing other kinds of nonoperating care such as pain-care management.
4. The rate of return to specializing in anesthesia will decline. (It is probably already starting to decline.) The number of applicants will decrease as potential students realize that the future in anesthesiology is not what it was in the 1980s. The reduction in the number of slots will almost inevitably lead to a significant reduction in the number of anesthesia programs around the country.

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TESTIMONY
OF
JAN STEWART, CRNA, ARNP
ON BEHALF OF THE
AMERICAN ASSOCIATION OF NURSE ANESTHETISTS
BEFORE THE
HOUSE JUDICIARY COMMITTEE

June 22, 1999

AMERICAN ASSOCIATION OF NURSE ANESTHETISTS
ANTITRUST TESTIMONY
HOUSE JUDICIARY COMMITTEE
June 22, 1999

Chairman Hyde, members of the Judiciary Committee, good morning. My name is Jan Stewart and I am a certified registered nurse anesthetist and President-elect of the American Association of Nurse Anesthetists ("AANA"). I am pleased to be testifying today regarding potential changes to the federal antitrust laws.

INTRODUCTION

The AANA is the professional association that represents over 27,000 certified registered nurse anesthetists ("CRNAs"), or 94 percent of the practicing nurse anesthetists in the United States. AANA appreciates the opportunity to provide our experience with respect to the need for vigorous enforcement of the antitrust laws.

As a leader in the advanced practice nursing community, we applaud your attention to the promotion of competition in the health care market place. However, AANA is extremely concerned about any weakening of the antitrust laws. We strongly believe that creating new antitrust exemptions for physicians could have severe unintended consequences and seriously undermine the larger goal of increasing competition in our health care system and providing affordable high quality care. Specifically, we believe that antitrust exemptions such as those currently being considered by the Committee would put nurse anesthetists at a serious and permanent competitive disadvantage with respect to contracting with health plans because it would :

- 1. Allow anesthesiologists to form cartels that discriminate against or exclude nurse anesthetists;**
- 2. Sanction attempts by anesthesiologists to eliminate competition between themselves and nurse anesthetists using spurious claims regarding patient health and safety;**
- 3. Drive up the cost of health care coverage for all Americans without any concomitant increase in the quality or availability of health care.**

We believe that strong antitrust laws and robust enforcement are crucial to protect competition and consumer choice in the health care system.

Part I of our testimony will provide important background about CRNAs and put their current antitrust disputes with physicians into a useful historical context. Part II will provide an analysis of H.R. 1304 and the reasons that AANA opposes it. Part III will discuss the recent history of anticompetitive conduct directed at CRNAs, focusing particularly on a recent American Medical Association Resolution directed against CRNAs and an ongoing antitrust action against anesthesiologists in Minnesota, where many CRNAs were dismissed from their positions with local hospitals as a result of what the Minnesota Association of Nurse Anesthetists alleges was an illegal conspiracy to exclude them from the market.

I. BACKGROUND INFORMATION ABOUT CRNAs

In the administration of anesthesia, CRNAs perform many of the same functions as physician anesthetists ("anesthesiologists") and work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers, health maintenance organizations, and the offices of dentists, podiatrists, ophthalmologists, and plastic surgeons. Today, CRNAs administer more than 65% of the anesthetics given to patients each year in the United States. CRNAs are the sole anesthesia provider in 65% of rural hospitals which translates into anesthesia services for millions of rural Americans. CRNAs are also front line anesthesia providers in underserved urban areas, providing services for major trauma cases, for example.

CRNAs provide high quality care at a fraction of the cost of anesthesiologists. According to a study conducted by the Medical Group Management Association and published in the October, 1995 issue of Anesthesiology News, in calendar year 1994 the median annual income for nurse anesthetists was \$72,001 but the median annual income for an anesthesiologist was \$244,600.

CRNAs have been a part of the surgical team since the advent of anesthesia in the 1800s. Until the 1920s, anesthesia was almost exclusively administered by nurses. Though CRNAs are not medical doctors, no studies to date have demonstrated a difference between CRNAs and anesthesiologists in the quality of care provided, which is the reason no federal or state statute requires that CRNAs be supervised by an anesthesiologist. Anesthesia outcomes are affected by such factors as the provider's attention, concentration, and organization, and not whether the provider is a CRNA or an anesthesiologist. That is why the Harvard Medical School Standards in Anesthesia focus on monitoring the patient; the standards are based upon data that indicate that anesthesia incidents are usually caused by lack of attention to detail and insufficient monitoring of the patient.

The most substantial difference between CRNAs and anesthesiologists is that prior to anesthesia education, anesthesiologists receive a medical education while CRNAs receive nursing education. However, once they enter the work force, both professionals perform roughly the same services: (1) preanesthetic preparation and evaluation; (2) anesthesia induction, maintenance and emergence; (3) postanesthesia care; and (4) peri-anesthetic and clinical support functions, such as resuscitation services, acute and chronic pain management, respiratory care, and the establishment of arterial lines.

There are currently 87 accredited nurse anesthesia education programs in the United States lasting between 24-36 months, depending upon the university. As of 1998, all programs offer a master's degree level for advance practice nurses, and these programs are accredited by the Council of Accreditation of Nurse Anesthesia Educational Programs which is recognized by the U.S. Department of Education.

- CRNAs as Anesthesia Competitors

By the end of the nineteenth century, two developments - the discovery and utilization of anesthesia and the discovery and development of asepsis - resulted in an enormous expansion of the numbers and types of surgeries performed. Consequently, hospital construction flourished as the need grew for operating rooms to accommodate aseptic surgery. Simultaneously, demand grew for anesthesia specialists to focus their attention on the anesthesia care of patients while a physician performed surgery.

Nurses, whose hallmark is monitoring vital signs and administering medications, were a natural choice to provide anesthesia. Physicians turned increasingly to sisters in Catholic hospitals, as well as to other registered nurses from a growing number of nurse training programs, to administer anesthesia with wide acceptance. World War I accelerated the demand for qualified CRNAs. Advances made in medications and equipment and nurse anesthesia education during the war contributed to the nurse anesthetists' dominant position in the anesthesia services field.

Even before World War I, however, the growth and acceptance of the nurse anesthesia profession and its training programs provoked anticompetitive reactions from anesthesiologists. As early as 1911, in a harbinger of future anti-nurse anesthetist activity, counsel for the New York State Medical Society declared that the administration of an anesthetic by a nurse violated the law of the State of New York. The following year, the Ohio State Medical Board passed a resolution stating that only registered physicians could administer anesthesia.

Early efforts to crush the nurse anesthesia profession gained momentum as anesthesiologists organized in their opposition to nurse anesthetists. In 1915, anesthesiologists founded the Interstate Association of Anesthetists ("IAA") which successfully petitioned the Ohio State Medical Board to withdraw recognition of Cleveland's Lakeside Hospital as an acceptable training school for nurses on the grounds that Lakeside's use of nurse anesthetists violated the Ohio Medical Board Act. Nurses and prominent surgeons alike protested the board's decision, and succeeded in having it reversed.

Similarly, in 1917, the Kentucky State Medical Association, with prompting from organized anesthesiologists, passed a resolution prohibiting members from employing nurse anesthetists. In a test lawsuit brought by a nurse anesthetist, the Kentucky Court of Appeals ultimately rejected the proposition that the administration of anesthesia by a nurse constituted the unauthorized practice of medicine.

In 1921, another anesthesiologist group, the American Association of Anesthetists, commenced a boycott by adopting a resolution prohibiting its members from teaching nurse anesthetists.

Anesthesiologists also moved into the political arena, supporting legislation which would prohibit qualified nurse anesthetists from administering anesthesia.

Unlike anesthesiologists, the American College of Surgeons, comprised of physicians who utilized nurse anesthetists, opposed legislative prohibitions of nurse-administered anesthesia. In a 1923 resolution, they opposed all legislative enactments which would prohibit qualified nurses from administering anesthesia.

Surgeon support of nurse anesthetists, however, did not stop the anesthesiologists' efforts to keep nurse anesthetists from practicing their profession. In 1933, anesthesiologists associated with the Los Angeles County Medical Association brought a lawsuit against a nurse anesthetist claiming that nurse anesthetists' administration of anesthesia constituted the illegal practice of medicine. As had other courts, the California court found that the administration of anesthesia by nurse anesthetists was not the practice of medicine.

In 1937, the American Society of Anesthesiologists ("ASA") was formed. (The American Association of Nurse Anesthetists had been founded in 1931). Immediately after its inception, the ASA presented a master plan for the eventual elimination of nurse anesthesia to the American College of Surgeons. The plan specified that nurses should not be permitted to continue to provide anesthesia. It also provided, inter alia, that a provision should be included in the Minimum Standards of Hospitals (the forerunners of the Joint Commission on Accreditation of Hospitals' standards) directing that the department of anesthesia in each hospital shall be under the direction and responsibility of a well-trained physician anesthetist. The plan cautioned, however, "that no legislation should be forced until physician anesthetists can take over the work in a competent way."

World War II increased the number of anesthesiologists. See the discussion in United States of America v. The American Society of Anesthesiologists, 435 F. Supp. 147, 150 (SDNY, 1979). After the war, the anesthesiologists, as they sought to establish themselves in a civilian economy, renewed their activities against CRNAs. Between 1946 and 1948, the ASA conducted a campaign to discredit CRNAs in the eyes of the public. The campaign was successful in reducing the numbers of nurses attending nurse anesthesia training programs. The campaign was halted when the American Medical Association, the American College of Surgeons, and the Southern Surgical Society expressed their opposition to the ASA's negative publicity, and expressed their support of, and continued intention to utilize, CRNAs.

Attempts to eliminate CRNAs have often been more subtle. For example, in 1947 the ASA adopted an "ethical principle" prohibiting members in good standing from participating in nurse anesthesia programs and from employing or utilizing CRNAs. Measures to enforce the ethical guidelines included the threat to revoke the American Board of Anesthesiology certificates of physicians training nurse anesthetists.

- The Need for Vigorous Antitrust Enforcement

Based on historical and recent experience, the AANA believes that strong antitrust laws and enforcement serve to protect competition between anesthesiologists and CRNAs. CRNAs provide the same services as anesthesiologists with the same high degree of care. In the market for health services, a market which is widely considered complex and imperfect by economists, this sort of direct competition between rival professional groups should be vigorously defended. While many CRNAs practice in an anesthesia team which includes anesthesiologists and other ancillary support staff, CRNAs also practice as independent providers and receive direct reimbursement from multiple payors, as allowed by federal law. Independent CRNAs may function as independent contractors -- negotiating the best price for the service with different health entities. Therefore, many CRNAs compete directly with their physician colleagues -- anesthesiologists. Because of the prevalence of insurance in the health care field, recipients of anesthesia services are seldom the direct payors while physicians benefit from tremendous influence with insurance companies and others who actually pay for health care services. For this reason, the threat of swift and vigorous enforcement of the federal antitrust laws and the deterrent effect that *those laws have* on anticompetitive conduct are the most important protections that CRNAs have against anticompetitive conduct by physicians who may seek to exclude them from the market because they are lower cost competitors. In light of the power and influence of the medical community on staffing decisions, weakening the antitrust laws by new and sweeping immunity for negotiations between health care professionals and health care plans could undermine the ability of CRNAs to compete with anesthesiologists, or any other similarly positioned health professional.

Further, the current antitrust laws serve to protect the ability of other types of established health professionals to offer competitive health services. These groups include the nurse-midwives who provide obstetrical care to women in need; optometrists who provide post-op cataract eye care; occupational therapists who diagnose and provide rehabilitation care; and speech-language pathologists. It is no exaggeration to say that the antitrust laws have been a major force enabling nonphysician health professionals to compete with physicians when they provide comparable services. Such competition has been an enormous boon to consumers and third party payors who benefit from having a wider choice of highly qualified providers.

II. AANA's OPPOSITION TO THE ANTITRUST EXEMPTIONS IN H.R.1304

Representative Tom Campbell (R-CA) has introduced the Quality Health-Care Coalition Act of 1999 (H.R. 1304), a bill that would weaken the current antitrust laws when applied to health care providers. **AANA is OPPOSED to H.R. 1304**, as well as any legislative effort that would interfere with competition between health care providers, and threaten the ability of CRNAs to compete on fair and equitable terms with anesthesiologists.

If enacted H.R. 1304 would provide new and sweeping antitrust immunity for negotiations between health care professionals and health care plans. The bill's stated goal is to level the playing field between managed care plans and health care providers with respect to reimbursement and the terms and conditions of employment. In pursuit of that goal, the bill exempts negotiations between health care providers and plans from the reach of federal and state antitrust laws, regardless of whether such negotiations include exclusionary or unreasonable demands by rival providers, such as anesthesiologists.

The bill has two main provisions. The first provision immunizes negotiations between groups of health care professionals (of any size or composition) and a health plan regarding the terms of a contract to provide health care items or services covered by the plan. It does so by extending the same antitrust protections to those negotiations as currently apply to bargaining units recognized under the National Labor Relations Act ("NLRA"). Such protections are generally referred to as the labor antitrust exemptions.

The second provision exempts actions taken in good faith reliance on the first provision from antitrust criminal sanctions, civil damages, fees, and penalties beyond actual damages incurred. It also provides that the first provision shall not confer any right to participate in any collective cessation of *services* to patients not otherwise permitted by law. Although the language on "cessation of services," *i.e.* group boycott, is not entirely clear, it does suggest that health care providers could collectively take measures that would affect patients access to care, such as refusing to accept a plan's reimbursement.

AANA Opposes H.R. 1304 because enactment of the bill would:

- Eliminate Opportunities for CRNAs to Compete: The bill would have the effect of making it more difficult for CRNAs to compete with anesthesiologists for contracts with health care plans. That is because the bill would provide blanket antitrust immunity for bargaining demands by anesthesiologists that health plans impose significant limitations on practice opportunities for CRNAs or exclude them from the plans entirely.

Under the bill, otherwise *per se* illegal conduct that occurs in the course of negotiations with health plans, such as price fixing, group boycotts, tying arrangements and customer or market allocation, would be entitled to immunity under the antitrust laws. The bill's wide ranging immunity would, for example,

permit health care professionals to make concerted demands about how much they should be paid for their services, who should be permitted to provide designated services and the terms and conditions under which designated services should be reimbursed.

Specifically, for CRNAs the bill's immunity would remove any legal bar to demands by anesthesiologists that CRNAs be excluded from a health plan because, for example, they fail to meet arbitrary licensing criteria, or that CRNAs be permitted to provide services for a health plan only on restrictive terms and conditions, such as costly and unnecessary supervision requirements.

- Eliminate Legal Incentives to Compete: The antitrust laws are an essential tool for CRNAs and other nonphysician providers to counteract the influence of physicians. For CRNAs, the antitrust laws not only deter anticompetitive conduct by rival providers and health plans, they also provide a powerful tool to combat anticompetitive conduct that threatens marketplace competition.

The Act removes the antitrust laws as a deterrent to anticompetitive conduct when such conduct occurs in the course of negotiations with a health plan. In so doing, it eliminates any incentive that anesthesiologists have, under the antitrust laws, to compete with CRNAs on a fair or equitable basis and replaces it with an irresistible opportunity to collude on restrictive and exclusionary bargaining demands aimed squarely at excluding CRNAs' access to health plans.

- Undermine Nondiscrimination Requirements: The Balanced Budget Act of 1997 ("BBA") included important nondiscrimination requirements for nonphysician providers. Specifically, the BBA prohibited Medicare+Choice plans from discriminating against CRNAs solely on the basis of their state license or certification with respect to participation, reimbursement or indemnification. However, the BBA also stated that such nondiscrimination requirements did not prohibit Medicare+Choice plans from including providers only to the extent needed to meet the requirements of its patients or from establishing quality and cost control measures consistent with its responsibilities.

Under the bill, anesthesiologists would be permitted to make concerted negotiating demands to Medicare+Choice plans that could effectively circumvent the nondiscrimination requirements. For example, they could negotiate restrictive educational or other professional criteria as a condition of participation, such as a residency in anesthesiology, which would have the effect of excluding CRNAs from the plan.

- Increase the Cost of Health Care and Harm Patients. The bill will inevitably increase the cost of health care by permitting high cost providers, such as anesthesiologists, to use their market power to increase their own reimbursement rates at the expense of more economic and efficient providers, such as CRNAs.

Eliminating competition in this manner will also harm patients. Our nation's health care system operates on the promise that patients will benefit most in terms of quality, cost and access to care when there is vigorous competition between providers, such as CRNAs and anesthesiologists. The bill will effectively undermine that competition by eliminating the antitrust laws as a deterrent to even the most egregious anticompetitive negotiating demands by providers bent on excluding or limiting the scope of practice for CRNAs.

There is no level playing field for many CRNAs. The fact is that physicians still wield much greater power and influence with their fellow physicians and in the marketplace. And, based on past experience CRNAs can expect them to use that power to protect their jobs and their incomes as the industry downsizes to become more efficient.

The antitrust laws are an essential tool for CRNAs and other nonphysician providers to counteract the power and influence of physicians and hospitals. That is why AANA has grave concerns about the antitrust exemptions for health care professionals in H.R. 1304.

III. NURSE ANESTHETISTS HAVE FREQUENTLY BEEN VICTIMIZED BY ANTICOMPETITIVE CONDUCT ON THE PART OF PHYSICIAN COMPETITORS

Current practices in the field of anesthesia do not reflect the normal workings of the marketplace. Economics alone would suggest that hospitals would be anxious to use lower cost providers, such as nurse anesthetists, in order to reduce their costs, and thus their prices to patients and third-party payors. However, that is not always the case. Anesthesiologists have repeatedly used their influence to keep prices high by, for example, convincing hospitals to terminate nurse anesthetists so that the anesthesiologists would not face price competition. This is not the way the market should work or that our health care system should work. However, unless those most immediately affected by anticompetitive conduct -- nurse anesthetists -- are able to bring suit successfully under the antitrust laws, consumers will be forced to pay higher prices and, in some cases, have fewer choices of services, such as not being able to receive an epidural block during childbirth.

There are many examples of anticompetitive conduct that affects the ability of nurse anesthetists to compete for patients. Passage of H.R. 1304 would refocus much of this conduct to negotiations with health care plans, where discriminatory and anticompetitive restrictions could become part of the terms and conditions of participation and would act as an insuperable barrier to entry for CRNAs.

- Anticompetitive Conduct Directed Toward CRNAs

Attempts have been made to keep CRNAs from competing with anesthesiologists by creating various barriers to practice. Examples of barriers to practice include: (1) hospital medical staff bylaws that deny CRNAs clinical practice privileges, (2) restrictions on CRNAs clinical practice privileges, (3) the promulgation of inaccurate information about a surgeon's liability for CRNAs, (4) the formation of large anesthesiologist groups that use their increased control or influence with hospitals and health plans to limit or eliminate competition from CRNAs, and (5) exclusive contracting by powerful providers, such as hospitals. Whether specific barriers to CRNA practice constitute anticompetitive behavior under the antitrust laws obviously depend on the facts of each case. However, CRNAs need to be able to use the antitrust laws to the fullest when practice barriers result from attempts to price-fix, monopolize, or boycott. H.R. 1304 would eliminate the antitrust laws as an effective deterrent when anticompetitive conduct occurs during the negotiation process with health plans.

1. Hospital Medical Staff Bylaws Which Deny CRNAs Clinical Practice Privileges

Some physicians have created hospital medical staff bylaws that effectively eliminate the opportunity for independent CRNA practice. In one such case, the hospital, upon recommendation of a group of anesthesiologists, changed its bylaws to state that "nurse anesthetists could only practice in the institution if they were employees of the physician anesthesiologists." This bylaw effectively restricts an independent CRNA from applying for medical staff clinical practice privileges. Without the opportunity to obtain medical staff clinical practice privileges at a hospital, independent CRNAs do not have the ability to administer anesthesia to patients in that facility -- regardless of permission by state law -- and would have to become employees of an anesthesiologist group or some other entity in order to provide anesthesia services.

This kind of practice restriction would have costly consequences for consumers and third-party payors. That is because hospitals will almost certainly have to pay more for CRNAs who are employees of anesthesiologists than for independent CRNAs.

2. Restrictions on Clinical Practice Privileges of CRNAs

Even where CRNAs have the right to practice, in many institutions there have been situations where anesthesiologists, through the medical staff, have artificially restricted their scope of practice. If their scope of practice is limited, then CRNAs cannot compete with unlimited, "full service" anesthesiologists. Restrictions on scope of practice have included refusals to grant clinical practice privileges for regional anesthesia, insertion of invasive monitoring lines, postoperative pain management of patients, and refusal to allow administration of an epidural injection. Other CRNAs experience unnecessary limitations on which types of patients they may treat. These restrictions on clinical practice privileges are not related to education, ability or to what state law permits, but rather to an attempt to limit competition.

3. Promulgation of Inaccurate Information about a Surgeon's Liability for CRNAs

It is difficult for CRNAs to compete in the market when anesthesiologists use inaccurate information to persuade surgeons not to utilize CRNA services. In one such situation in Southern California, an anesthesiologist sent promotional and marketing letters to plastic surgeons, ophthalmologists and other physicians stating that the surgeons had increased liability if they used a CRNA rather than an anesthesiologist. It is important to understand that typically in cosmetic plastic surgery, the patient pays for the procedures, as insurance does not cover such

operations. Thus, plastic surgery is one of the few areas of health care where the market is sensitive to price. Plastic surgeons, recognizing the competitive pricing and high quality of care provided by CRNAs, have utilized CRNAs as practitioners for many years. However, inaccurate information regarding liability of the surgeons for care provided by CRNAs could have had a significant adverse influence on a surgeons' use of nurse anesthetists.

Anesthesiologists have also raised the specter of an increase in liability risk if CRNAs are not supervised by anesthesiologists. The law governing the liability of a surgeon for the negligence of a nurse anesthetist is precisely the same as the law which governs the liability of a surgeon for the negligence of an anesthesiologist. Liability depends on the facts of each case. Nonetheless, anesthesiologists continue to make such statements to discourage surgeons from working directly with CRNAs.

In this regard, the American Association of Nurse Anesthetists (AANA) has been engaged in a decade long battle to persuade the Health Care Financing Administration (HCFA) to remove the physician supervision requirement in the Medicare Conditions of Participation for Hospitals and Ambulatory Surgical Centers (ASCs). Given the anesthesiologists misuse of supervision requirements to create false perceptions about physician liability, HCFA was asked to remove the supervision requirement. HCFA proposed to do so in December, 1997. The proposed rule is still pending, in part due to the strong opposition generated by the American Society of Anesthesiologists (ASA). AANA has had to seek legislative relief so that the federal government will defer to the states on the issue of physician supervision of CRNAs (S. 866/H.R. 804) as it does in virtually every other area of health care.

4. Formation of Large Anesthesiologist Groups

Formation of anesthesiologist groups that have the potential to control a large share of the market also pose a threat to competition. Such groups are likely to have enough market power to force hospitals and other facilities to boycott low cost providers, such as CRNAs. As in any monopoly or near monopoly situation, the result is that consumers pay higher prices and have fewer choices of services.

Large anesthesiology groups have been able to monopolize anesthesia services in hospitals in a few major metropolitan areas. In those situations, competitors are likely to be prohibited from gaining access to the hospital, which eliminates competition altogether.

In 1994, there was a merger of two anesthesiologist groups (Middle Tennessee Anesthesiology, P.C. and Anesthesiology Consultants of Nashville, P.C.), both of

which served metropolitan Nashville, Tennessee and surrounding Davidson County. The new group, called Anesthesia Medical Group ("Group"), includes nearly 50% of the non-teaching anesthesiologists serving the metropolitan Nashville area. The Group also employs 105 of the 175 CRNAs practicing in the same area.

In the Nashville area there are 3,906 staffed hospital beds distributed among 12 hospitals. The Group is the sole anesthesia provider in two hospitals comprising one third of the available staffed hospital beds in Nashville. In a third hospital, with 571 staffed beds, the group does not have an exclusive arrangement, but provides approximately 65 percent of the anesthesia.

In total, the Group has approximately 50% of the practicing anesthesiologists in the area, controls 60% of the CRNAs in the area, and has exclusive or nonexclusive access to nearly one half of the areas staffed hospital beds. The market power of the Group appears to be well beyond the safety zones established in the Antitrust Division's and the FTC's Policy Statements for physician joint ventures, and because of that may have the ability to increase prices and reduce services for patients in the area.

- Exclusive Contracting by Powerful Providers

Texoma Medical Center, Inc. ("TMC"), a non-profit corporation that operates a hospital in Denison, Texas, provides an example of how exclusive contracting by a powerful provider can undermine competition from CRNAs. It is estimated that TMC provides medical care and treatment and surgical facilities for approximately 95 percent of the residents of Denison, Texas. TMC has approximately 15 to 20 surgeons on staff and has extended clinical privileges to four anesthesiologists and four CRNAs.

In January 1994, TMC's hospital administrator and CEO announced the hospital's intention to enter into an exclusive provider agreement "with a single source for all anesthesia care required by surgeons and patients of TMC." In conjunction with this announcement, certain physicians were requested to submit a proposal to the hospital for an exclusive provider agreement. No request for proposal was made to any of the CRNAs at the hospital with staff privileges, even though CRNAs charge less for anesthesia services than anesthesiologists. Presumably, CRNAs would have been allowed to continue providing services at the hospital only if they were employed by the exclusive provider group.

In order to keep the market competitive, three CRNAs and one anesthesiologist practicing at the hospital announced their intention to bring an antitrust suit against the hospital for exclusive dealing. The hospital subsequently dropped its exclusionary plan, but it might not have done so if the CRNAs had been hamstrung in their ability to bring an antitrust suit.

- Attempts by the American Medical Association to Restrict Practice Opportunities for CRNAs

The American Medical Association (AMA) has attempted to orchestrate a concerted campaign to restrict practice opportunities for CRNAs. In December 1998, its House of Delegates adopted a resolution calling for the AMA's support of legislative and regulatory proposals defining anesthesia as the practice of medicine. (AMA) Resolution 216. Specifically, the AMA Resolution 216 states:

1. "That anesthesiology is the practice of medicine."
2. "That the American Medical Association seek legislation to establish the principle in federal and state law and regulation that anesthesia care requires the personal performance or supervision by an appropriately licensed and credentialed doctor of medicine, osteopathy, or dentistry."

What the AMA meant to accomplish by stating that "anesthesiology is the practice of medicine," is to limit the administration of anesthesia *exclusively* to anesthesiologists and to ensure that CRNAs -- when they are permitted to practice at all-- are supervised by anesthesiologists at all times and in all settings. Such an interpretation would seriously restrict the ability of CRNAs to practice independently in settings, such as office-based or free-standing surgical centers, where the only physician available is likely to be the operating surgeon. It would also restrict their ability to provide anesthesia services in rural areas where no physician may be available.

Currently, the AMA has no way to put its unfair and discriminatory resolution into effect, except to call upon lawmakers to adopt such restrictions. However, under H.R. 1304, nothing would prevent AMA members from insisting that health plans adopt such a restrictive interpretation of the administration of anesthesia in order to exclude CRNAs from their plan or severely limit their participation. Such a restriction would penalize CRNAs and increase health care costs by eliminating healthy competition between anesthesiologists and nurse anesthetists and reducing the options now available to patients, payers and physicians to choose, if they desire, to obtain anesthesia services from independent CRNAs.

- Attempts at the State Level to Restrict the Scope of Practice for CRNAs

In addition to the AMA Resolution, there has been an increase in activity at the state level to circumscribe the practice opportunities of CRNAs. Many of these restrictions which are being hard fought in state legislatures, medical board and the like. Such restrictions could, however, be put into effect under H.R. 1304 through negotiations with health plans. These proposed restrictions include:

- Requiring CRNAs to be physician supervised in states that do not currently require such supervision.
- Requiring that anesthesiologists supervise CRNAs in states that already require physician supervision by requiring anesthesiologist supervision of CRNAs when anesthesiologists are "available;" by discouraging surgeons from working with CRNAs by requiring that physicians who supervise CRNAs meet criteria possessed only by anesthesiologists such as advanced education and training in anesthesia or hold "appropriate credentials."
- Requiring CRNA practice to be jointly regulated by the board of medicine and the board of nursing, rather than the board of nursing alone, and
- Reducing CRNAs' scope of practice, e.g., limiting the types of anesthesia that a CRNA can perform.

- Antitrust Actions Brought by CRNAs

CRNAs have brought actions against anesthesiologists for restricting competition. Although the antitrust exemption proposed in H.R. 1304 would not immunize all the types of exclusionary conduct catalogued below, these cases illustrate the fact that anesthesiologists have attempted to exclude CRNAs from the health care market using unfair and anticompetitive tactics. H.R. 1304 would immunize those same tactics when anesthesiologists employed them in connection with their negotiations with health care plans.

In Oltz v. St. Peter's Community Hospital, 861 F.2d 1440 (5th Cir. 1988), Oltz, a nurse anesthetist, sued four anesthesiologists and the hospital that gave them an exclusive contract to provide anesthesia services, under the antitrust laws. Oltz charged the anesthesiologists and the hospital with a group boycott, which can be a *per se* violation of the antitrust laws. The anesthesiologists settled before going to trial.

In affirming the district court's finding that the hospital joined the anesthesiologists' conspiracy to terminate Oltz's billing contract, the Ninth Circuit noted that the anesthesiologists had "pressured the hospital at St. Peter's to eliminate Oltz as a direct competitor." The court found that the anesthesiologists had threatened to boycott St. Peter's unless Oltz's independent billing status was terminated and that the anesthesiologists annual earnings at the hospital increased by forty to fifty percent after Oltz was terminated.

In Bhan v. NME Hospitals, Inc. 929 F. 2d 1404 (USCA Ninth Cir., 1991) a nurse anesthetist and an anesthesiologist were anesthesia providers in a small hospital in Manteca, California. Surgeons at the hospital decided to attract another anesthesiologist. When the third provider arrived the nurse anesthetist alleged that the anesthesiologist who was to be replaced tried to save his job by suggesting to the hospital administration an all-physician anesthesia policy and the elimination of the CRNA. The CRNA brought suit under the antitrust laws arguing that a physician only anesthesia policy was a coercive boycott. The Ninth Circuit ruled that nurse

anesthetists and anesthesiologists directly compete for purposes of the antitrust laws but the trial court held that the Hospital's conduct had to be evaluated under the rule of reason and the case was dismissed.

In Anesthesia Advantage, Inc. v. Metz, 708 F. Supp. 1171, 1175 (10th Cir. 1990), four nurse anesthetists in the Denver, Colorado area and their professional corporation, The Anesthesia Advantage, Inc. ("TAA"), brought suit against several anesthesiologists and Humana Hospital. The nurse anesthetists alleged *per se* violations of the antitrust laws, including price fixing, market allocation and a group boycott. The charges were based on (1) a hospital-instituted "call schedule" for anesthesiologists and the anesthesiology staff's recommendation to adopt guidelines for supervising nurse anesthetists; (2) a conspiracy to induce another hospital to reject a fee-for-service proposal by TAA to provide out-patient ambulatory surgery anesthesia on pre-arranged days; and (3) an attempt to persuade a third hospital to reject a proposal that the hospital use TAA for an obstetric epidural anesthesia program.

The nurse anesthetists alleged that they were "illegally squeezed out of business by anesthesiologists because the presence of CRNAs forced down the market price for anesthesiologist services."

The Tenth Circuit Court of Appeals reversed the trial court's dismissal of the case, and some of the defendants eventually settled the case, by among other things, agreeing that they would not interfere in the future with CRNAs' right to practice anesthesia.

- The Current Case in Minnesota

A recent case that illustrates the unfair and anticompetitive tactics employed by anesthesiologists to exclude CRNAs is that brought by the Minnesota Association of Nurse Anesthetists (MANA). MANA has alleged that a group of anesthesiologists sought to eliminate CRNAs as lower cost competitors and to seize unfettered control over the market in the pricing of anesthesia services; as a result of this scheme many CRNAs at three of the largest Minnesota hospitals were fired from their jobs.

MANA is currently engaged in a lawsuit which seeks to bring this unlawful conduct to an end and to restore competition to the marketplace. MANA is currently appealing the dismissal of its complaint.

Minnesota nurse anesthetists, in their suit, have alleged that for years, anesthesiologists have allocated territories between themselves and engaged in organized boycotts of both individual CRNAs and CRNA groups. MANA alleges that beginning ten years ago and lasting until very recently, there had been virtually no competition between any of the anesthesiology groups in the state and that groups had allocated the various hospitals among themselves and entered into de facto or actual exclusive agreements with those hospitals.

CRNAs are natural competitors with anesthesiologists for the provision of anesthesia services. Despite this fact, in Minnesota and many other states, anesthesiologists make over four times as much money as CRNAs. The reason for this, at least in part, is that in Minnesota anesthesiologists have established and maintained substantial market power through a number of organized efforts which have successfully put them in a position to control anesthesia pricing and the method in which anesthesia is provided.

Unfortunately, the result in many hospitals is that the method by which anesthesia is provided is based largely upon the reimbursement potential and the profitability to the anesthesiologist. The allegations in the Minnesota suit exemplify how this power works against competition. The annual average income of an anesthesiologist in the Twins Cities area is believed to exceed the average in every other state, going as high in some cases as one-half million dollars or more.

It is our understanding that in some cases, and possibly many cases, the cost of the anesthesia services provided in connection with a surgery may exceed the cost of the surgery itself by a substantial amount. This is because the anesthesiologists have created barriers to entry and foreclosed the market for anesthesia not only to CRNAs but to competing anesthesiologists who might seek to enter the Minnesota market and compete on pricing. The allegations and evidence in the law suit suggest that:

1. Anesthesiologists have misrepresented government requirements for reimbursement as quality of care requirements. In other words, through the smoke screen of patient quality of care, they have imposed requirements that anesthesiologists be involved in, or at least get paid for, virtually every aspect of the anesthesia procedure, even though many of these aspects of the anesthesia procedure can be performed and are performed by CRNAs alone. In particular, federal and state laws, as well as AANA's certification requirements, permit CRNAs a wide scope of practice to provide virtually any anesthesia service. As stated earlier, CRNAs are the sole anesthesia provider in 75% of rural hospitals and therefore, provide all the services.

Nevertheless, under the guise of patient safety, anesthesiologists have introduced limitations on CRNAs' scope of practice. These limitations appear in hospital by-laws, written hospital procedures or in some cases, in unwritten hospital policies. For example, anesthesiologists have restricted CRNAs' ability to (1) perform regional anesthesia, (2) place arterial lines, and (3) place epidurals. AANA believes it is not a coincidence that Medicare and other third party payors pay substantial amounts of money for these procedures. Anesthesiologists who attempt to allow CRNAs to perform such procedures have been threatened by other anesthesiologists and often their state associations. Interestingly, procedures such as intubation and extubation, which are equally challenging but do not have a corresponding high rate of reimbursement, are routinely performed by CRNAs without objection by anesthesiologists.

2. Anesthesiologists have engaged in conspiracies with hospital personnel to prevent CRNAs from practicing on an independent basis in hospitals, downgrading CRNA status as health care providers, and other restrictive practices which impede the CRNAs' ability to independently provide anesthesia services. Anesthesiologists have also limited CRNAs' scope of practice.

Anesthesiologists' control of the market has extended to attempts to eliminate a supply of CRNAs in the Minnesota market. Anesthesiologists have recently refused to assist the school for CRNAs which provides new graduate CRNAs -- again under the guise of quality of care concerns. Also, the anesthesiologists' refusal to permit education in other aspects of anesthesia has threatened student ability to meet requirements to become "certified" as certified registered nurse anesthetists (CRNAs). AANA requires advanced clinical experience in these areas before it will extend certification.

Perhaps the most egregious example of the anesthesiologists' attempt to obtain a stranglehold on the market for anesthesia has occurred in the past two years during which the anesthesiologists have entered into a conspiracy to eliminate CRNAs altogether in Minnesota as economic competitors and to force them to work directly for the anesthesiologists. In this way, they can ensure that while CRNAs are still performing the work for them, CRNAs will be unable to affect or compete in the areas of pricing and other quality of service concerns.

The law suit also alleges that through a campaign which included: (1) the use of improper and fraudulent billing to Medicare and other third party payers, (2) widespread dissemination of inaccurate and misleading statements disparaging CRNAs and their abilities to practice anesthesia, and (3) the limitations on scope of practice referred to above, anesthesiologists have coerced four of the major hospitals in the state of Minnesota including Unity Hospital, Mercy Hospital, St. Cloud Hospital, and Abbott-Northwestern Hospital, to terminate all of their CRNA employees and to compel them to work for the anesthesiologists. Because the anesthesiologists control the market for anesthesia, CRNAs were left with the choice of leaving their families, selling their houses and seeking employment outside the state.

Had it not been for the lawsuit brought by MANA, it would not be an exaggeration to state that by now competition in the area of anesthesia services between the CRNAs and the anesthesiologists would be non-existent.

Just a Turf Battle?

No doubt there will be some who believe that our concerns are unjustified, simply the problems of a turf battle between health care professionals. To a large degree, this is a turf battle, but an important one in which today's consumer has a major stake. If the antitrust laws are weakened, it is not just nurse anesthetists who will be pushed out of the

health care market, it is yet another consumer choice which falls by the wayside and a good possibility that anesthesia prices could needlessly rise.

Consider the comments of ASA President John B. Neeld, Jr., M.D. In his article "Market Factors Demand the Evolution of the Care Team", in the Georgia Society of Anesthesiology Newsletter (date uncertain). He clearly sets out his ideas about the role of anesthesiologists and nurse anesthetists in the health care system. He said in part:

"In addition to the reduction in demand for services and the reduction in reimbursement for those services, the supply side of Anesthesia personnel has also changed. There is now an excess number of Physician and Anesthetists competing for the same positions. An excess supply has brought the compensation levels that new Anesthesiologists are willing to accept close in the salary levels enjoyed by Anesthetists that the differential is negligible, particularly when one places a reasonable value on the greater skills, education, and professionalism that the physicians bring to a practice. Replacement of Anesthetists by Anesthesiologists is by no means a death knell for these personnel; most practices will always have a need for a certain number of non-physician practitioners to provide economically viable coverage for underutilized anesthetizing locations. Doing the right thing is frequently unpopular; doing the wrong thing in this case will deprive patients of the opportunity for improved care and deprive our specialty of the opportunity for continued improvements in our knowledge base and technology that are dependent upon the maintenance of our Educational and Research Institutions and upon the continued attraction of the best and brightest medical students into Anesthesiology. Each of us must step forward and do the proper thing for our patient population, our Specialty, and for Anesthesiologists and Anesthetists. Anesthetists who add value to practices and are loyal to the true concept of a Care-Team should be retained and rewarded; those who do not should be replaced by our Young Physician Colleagues." (Emphasis added)

We think Dr. Neeld clearly states the agenda of the American Society of Anesthesiologists (ASA) which appears to be: CRNAs who cooperate with us have their place but those who don't should be replaced by anesthesiologists. We don't know what other conclusion you could reasonably draw from Dr. Neeld's comments. Bottom line: play ball or be replaced.

That agenda, reinforced by the ASA's request to the AMA to issue a resolution that "anesthesia is the practice of medicine", continues to make the puzzle even more clear. And if this legislation were to be enacted, it would give the anesthesiologists the legal green light to move ahead and boycott, price-fix or engage in other illegal activities in order to push nurse anesthetists out of the market. This resolution has caused some organizations to contact AANA to inquire whether this requires them to employ only anesthesiologists.

But these issues are raised not only by CRNAs but in fact others as well.

In his book, Not What the Doctor Ordered, How to End the Medical Monopoly in Pursuit of Managed Care, (McGraw Hill, 1998) Jeffery C. Bauer, Ph.D., explains at length and in specifics, how organized medicine has, over the years, sought to constrain nonphysician providers from gaining a foothold in the healthcare delivery system. His chapter on nurse anesthetists and anesthesiologists provides an interesting perspective from a health care futurist and medical economist. I offer some excerpts to explain his position. He states in part:

“In the context of this chapter’s main theme, I have saved the best example for last. (To be clear and fair, it is the example, not the professional group, that is best. Nurse practitioners, nurse midwives, and nurse anesthetists are all excellent in their different areas of practice). The CRNA story illustrates perfectly the benefits of competition from qualified nonphysician practitioners and the harmful effects of doctors’ anticompetitive efforts to control the market. In particular, it shows why persistent enforcement of antitrust law, something very different from health reform, is needed to protect consumers’ welfare from doctors’ monopoly when acceptable substitutes are available. . .”.

“My reason for featuring the market for anesthesia services is actually quite strong from the economic perspective. Physicians may have been unsuccessful in their ongoing attempts to eliminate nurse anesthetists as an alternative, but they have been remarkably successful in depriving American consumers of the potential economic benefits of potential competition. In other words, doctors have controlled the market to their own economic benefit, which means consumers have been paying uncompetitive prices for anesthesia services. How else could one explain the fact that anesthesiologists have consistently earned more than twice as much as nurse anesthetists while providing the same service?”

“The principal measure of economic harm has been the fee that anesthesiologist receive for ‘supervising’ nurse anesthetists. Unable to prevent state legislatures from licensing CRNAs, anesthesiologists have used their influence with health insurance plans (often as owners or directors) to make sure that payment flowed through the doctor’s account. For years, many private health plans have had various schemes that allowed anesthesiologists to charge their full fee for services provided by CRNAs operating under their supervision. (The term is ‘medical direction’ in the arcane language of Medicare reimbursement. This technicality allows an anesthesiologist to be partially reimbursed for ‘medically directing’ up to four CRNAs at a time. It is nice work if you can get it . . . and having monopoly power helps.”

“You can easily guess the rest of the story: the doctor they pays the nurse anesthetist a lower amount for performing the service, and he pockets the often substantial difference. This difference between an anesthesiologist’s fee and the

cost of the CRNA who actually provided the service might be justifiable if supervision were necessary, but it isn't. This practice is a textbook example of economic exploitation. It is a sign of unwarranted economic power which makes consumers pay more than what is necessary or fair. It reminds me of featherbedding, the discredited labor practice of using more workers than are necessary. Thanks to modern technology and excellent training, CRNAs do not need medical 'supervisors' any more than railroads need superfluous brakemen and conductors riding in a caboose".

"Finally doctors have used their economic power to deny or restrict hospital privileges for nurse anesthetists. Even in states where CRNAs have full rights to independent practice and direct reimbursement, anesthesiologists have regularly prevented their nonphysician counterparts from having equal access to operating rooms, the site where most anesthesia is administered. This practice constitutes a significant barrier to entry, one of the key indicators of monopoly power in economic theory and antitrust law.

This brief look at the market for anesthesia services shows that medical monopolists have many ways to suppress competition, even when qualified nonphysician practitioners receive licenses for independent practice. CRNAs have achieved much of the recognition sought by other advanced practice nurses, but consumers are still denied a free, fully informed choice in the marketplace because doctors continue to defend 'captain of the ship' authority with the outdated argument that they are unique (i.e., better). The many successes of CRNAs in a still imperfect market remind us that the medical monopoly must be fought on many fronts.

To armchair economists, the story might seem to have a happy ending. Anesthesiologists' incomes have fallen dramatically in the past few years, which might be interpreted as a sign that competition has finally prevailed in this market. More than one force could be at work here, however, so do not jump to simple conclusions. Managed care has certainly exerted some downward pressure on money paid to hospital-based physicians. An oversupply of anesthesiologists is also believed to be a major explanatory factor. Anesthesiologists' professional associations are already working on plans to reduce the number of training positions and to restrict the entry of foreign medical graduates into residency programs.

These efforts must not become red herring that divert our attention from the market's long-term problems, unjustifiable restrictions on consumer choice and related barriers to entry. Believe me, anesthesiologists have not lost interest in this issue just because they have realized they are too numerous. They are pushing like never before to control CRNAs. Monopolists do not go down easily when their incomes are threatened. Intensive, anesthesiologist-led efforts to place restrictions on nurse anesthetists have been initiated within the past two years in

several areas of the country, including the bellwether states (in terms of health policy) like Ohio, Minnesota, New York, New Jersey, Pennsylvania, and Oregon.”

“A proposal made by the Oregon delegation to the 1997 mid-year meeting of the AMA House of Delegates serves as fitting proof that doctors are still fighting all advanced practice nurses to retain their monopoly power:

Whereas, Increasing pressure by special interest groups has persuaded state legislators to introduce legislation unjustifiably expanding scopes of practice of alternative and allied health workers; and Whereas, Many healthcare workers seek to legislate their ability to practice medicine, rather than obtain a high level of expertise and competence through medical school education and training; and Whereas, Medical decisions for patients are best made by medical doctors; and Whereas, There is considerable confusion on the part of the public and some legislators regarding the qualifications and training of healthcare workers versus medical doctors; and Whereas Education of the public and legislature needs to occur to replace confusion and ignorance with facts; therefore be it RESOLVED, That is the it is the policy of the American Medical Association to protect the public by supporting medical doctors against efforts advanced by alternative providers seeking increased medical control of patients by legislatively expanding their scopes of practice without physician directions and state boards of medical examiners oversight.”

Dr. Bauer concludes that the resolution was reaffirmed by the Delegates as a statement of existing AMA policy.

Conclusion

In conclusion, providing antitrust exemptions for physicians will harm nonphysician providers and their patients. That is because antitrust exemptions can and likely will be misused by physicians to discriminate against nonphysician providers with whom they compete for patients and for health care dollars.

Despite the fact that plain economics would suggest otherwise, many nonphysician providers are experiencing difficulty contracting with health plans because most, if not all, are controlled by physicians. Permitting physicians to obtain blanket antitrust immunity for their negotiations with health plans will make that situation worse and quite possibly foreclose those opportunities for CRNAs and other nonphysician providers completely. Many of the arguments made in the guise of “quality of care” are merely nothing more than a veiled attempt to grab greater control of the health care market and to enhance physician incomes.

Recent activity by the AMA and in state legislatures has made it clear to AANA that physicians are searching for ways to limit competition from nonphysician providers and will use any means at their disposal to accomplish those ends. The Congress and this Committee should not assist them by abolishing the antitrust laws that protect nonphysician providers from exclusionary and discriminatory treatment by physicians and health plans. To do so would undermine the health care system itself and penalize nonphysician providers and their patients by tipping an already unlevel playing field on its head in favor of physicians.

Thank you for your consideration of our views. I look forward to responding to your questions.

ATTACHMENTS

Quality of Care in Anesthesia

Types of Published Information Comparing
General Anesthesia Nurse Anesthetist and
Anesthesiologist Patient Outcomes

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American Association of Nurse Anesthetists

Quality of Care in Anesthesia

Synopsis of Published Information Comparing
Certified Registered Nurse Anesthetist and
Anesthesiologist Patient Outcomes

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Table of Contents

INTRODUCTION	1
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SECTION ONE

Summary of Pertinent Quality of Care Studies and Data	3
1. Bechtoldt Study	3
2. Forrest Study	4
3. Minnesota Department of Health Study	6
4. Centers for Disease Control	6
5. National Academy of Sciences Study	6
6. St. Paul Data	6

SECTION TWO

Anesthesiologist Distortions Concerning Quality of Care	9
1. Abenstein and Warner Article in <i>Anesthesia & Analgesia</i>	9
2. Silber Study in <i>Medical Care</i>	14
3. <i>New England Journal of Medicine</i> Articles (by Wiklund and Rosenbaum)	16
4. Silber Study in <i>Anesthesiology</i>	19

SUMMARY	26
---------------	----

BIBLIOGRAPHY

Selected references on the Quality of Anesthesia Care by Anesthesiologists and Nurse Anesthetists	27
--	----

APPENDIX

Nurse Anesthetists Professional Liability Premiums, Premium Changes from 1988 to 2001 (St. Paul Documentation)	28
---	----

Introduction

Nurse anesthetists have been providing quality anesthesia care in the United States for more than 100 years. In administering more than 65 percent of the anesthetics given annually, CRNAs have compiled an enviable safety record. No studies to date that have addressed anesthesia care outcomes have found that there is a significant difference in patient outcomes based on whether the anesthesia provider is a CRNA or an anesthesiologist.

The practice of anesthesia has become safer in recent years due to improvements in pharmacological agents and the introduction of sophisticated technology. Recent studies have shown a dramatic reduction in anesthesia mortality rate to approximately one per 250,000 anesthetics.

The fact that there is no significant difference regarding the quality of care rendered by anesthesiologists and CRNAs is not surprising: "[A]n understanding of the nature of anesthesia would lead one to expect this. The vast majority of anesthesia-related accidents have nothing to do with the level of education of the provider." [Blumenreich GA, Wolf BL. "Restrictions on CRNAs imposed by physician-controlled insurance companies." *AANA Journal*. 1986;54:6:538-539, at page 539.]

The most common anesthesia accidents are lack of oxygen supplied to the patient (hypoxia), intubation into the esophagus rather than the trachea, and disconnection of oxygen supply to the patient. All of these accidents result from lack of attention to monitoring the patient, not lack of education. In fact, the Harvard Medical School standards in anesthesia are directed toward monitoring, which reiterates the basic point — most anesthesia incidents relate to lack of attention to monitoring the patient, not lack of education.

As Blumenreich has stated:

Anesthesia seems to be an area where, beyond a certain level, outcome is only minimally affected by medical knowledge but is greatly affected by factors such as attention, concentration, organization and the ability to function as part of a team; factors towards which all professions strive but which no profession may claim a monopoly. See *id.* at page 539.

Section One

Summary of Pertinent Quality of Care Studies and Data

1. Bechtoldt Study

[Bechtoldt, Jr, AA. "Committee On Anesthesia Study. Anesthetic-Related Deaths: 1969-1976." *North Carolina Medical Journal*. 1981;42:253-259.]

A. Background

A 10-member Anesthesia Study Committee (ASC) of the North Carolina Medical Society reviewed approximately 900 perioperative deaths in that state over the eight-year period from 1969 to 1976. The ASC determined that 90 perioperative deaths were, to a certain extent, related to the administration of an anesthetic. The ASC did not study types of anesthesia-related outcomes other than death. Based on an ASC survey of hospitals, the ASC estimated that more than two million anesthetics were administered in North Carolina from 1969 to 1976.

The ASC defined "anesthetic-related" deaths as those in which the ASC determined that anesthesia was found to be a) the sole cause of death or b) the major contributing factor.

In categorizing cases, the ASC used information from death certificates and questionnaires completed by anesthesia providers of record. Based on that data, the ASC estimated that there had been one anesthetic-related death per 24,000 anesthetics administered.

The ASC used six different criteria to review the cases, including the following:

- type of anesthetic involved
- location where anesthesia was administered within the facility
- type of practitioner(s) involved in anesthesia administration
- surgical procedure or operation
- patient risk classification

B. Comparison of Outcome According to Provider Type

The ASC classified those who had administered anesthesia as follows:

- certified registered nurse anesthetist (CRNA) working alone
- anesthesiologist working alone
- CRNA and anesthesiologist working together
- surgeon or dentist
- unknown (in some of the cases, the type of practitioner administering the anesthetic was not identifiable based upon the information available to the ASC)

Bechtoldt reported that the ASC:

...found that the incidence among the three major groups (the CRNA, the anesthesiologist, and the combination of CRNA and anesthesiologist) to be rather similar. Although the CRNA working alone accounted for about half of the anesthetic-related deaths, the CRNA working alone also accounted for about half of the anesthetics administered. [page 257] [emphasis added]

Bechtoldt stated that the ASC's study included patients representing all risk categories. The study did not, however, address whether particular types of anesthesia providers (i.e., anesthesiologists or CRNAs) tended to encounter patients having particular risk factors. Because CRNAs working alone provided approximately half of the nearly two million anesthetics administered in the state during the period of the study, it is reasonable to believe CRNAs provided care to patients covering the full spectrum of physical status and anesthetic risk.

2. Forrest Study

[Forrest, WH. "Outcome - The Effect of the Provider." In: Hirsh, R, Forrest, WH, et al., eds. *Health Care Delivery in Anesthesia*. Philadelphia: George F. Stickley Company; Chapter 15. 1980:137-142.]

Forrest reviewed data that had been collected as part of an intensive hospital study of institutional differences that the Stanford Center for Health Care Research conducted. Forrest analyzed mortality and severe morbidity outcome data from 16 randomly selected hospitals, controlling for case-mix variations. The data concerned 8,593 patients undergoing 15 surgical procedures over a 10-month period (May 1973 through February 1974). Using that data, Forrest compared outcomes based upon type of anesthesia provider.

For study purposes, the hospitals were classified as having either:

1. primarily physician (anesthesiologist) providers (9 hospitals), or
2. primarily nurse anesthetist providers (7 hospitals).

Each of the 8,593 patients were "weighted" to reflect the progression or stage of disease at the time of surgery, and "the probability of developing postoperative morbidity and mortality, given the stage of the patient's disease." Forrest initially compared actual patient outcome to the outcome that would have been predicted based upon the patient's preoperative health status and the surgery performed. Compared with outcomes predicted, the actual results showed no significant difference in outcome between facilities having primarily nurse anesthetists or those having primarily physician anesthesiologists.

Forrest then looked at the data using three scales that differed based on definitions of "morbidity" applied to each scale. Slight differences between the two groups (i.e., primarily nurse anesthetist, or primarily anesthesiologist) were found, but the favored group varied according to the analysis criteria employed. That is, depending on criteria, sometimes the anesthesiologist-dominated group showed better outcomes, and sometimes the nurse anesthetist-dominated group fared better. After applying statistical tests to the results, Forrest stated:

Thus, using conservative statistical methods, we concluded that there were no significant differences in outcomes between the two groups of hospitals defined by type of anesthesia provider. Different methods of defining outcome changed the direction of differences for two weighted morbidity measures. [page 141] [emphasis added]

The Forrest study was presented at a 1977 symposium sponsored by the Association of University Anesthetists; the symposium dealt with the broader subject of "Epidemiology and Demography of Anesthesia." Official comments concluding this anesthesiologist-dominated proceeding (Chapter 25 of *Health Care Delivery in Anesthesia*, cited above) showed that the findings of Dr. Forrest, as well as others researching provider aspects of outcomes, caught some of the symposium participants off guard. As one commenter stated:

It was surprising that the stage of training of the anesthesiologist or administration of an anesthetic by a nurse anesthetist or anesthesiologist seemed to affect risk very little.... [page 220]

Still another physician commenter, who was chair of a university-based anesthesia department, articulated a reaction possibly shared by many of his colleagues in academia:

Dr. Forrest's very carefully done study showed no difference in outcome whether the provider was a nurse anesthetist or an anesthesiologist.... If we had to accept the data that there are no differences in outcome between anesthetics administered by anesthesiologists compared to nurse anesthetists, the consequences would be truly extraordinary. It would mean that we would have to question our very careers; we would have to question the value of anesthesia residency training programs; we would have to question organization in hospitals; we would have to question and reexamine projections for manpower needs in the future; we would have to question medical economics as they are projected right now. With some of the data presented to us [during the full symposium] we were very comfortable because they matched expectations.... Now in the study

comparing nurse anesthetists and anesthesiologists, we do not have this comfort. [pages 223-224]

3. Minnesota Department of Health Study

In 1994, the Minnesota Department of Health (DOH), as mandated by the state Legislature, studied the provision of anesthesia services by CRNAs and anesthesiologists. The department reached four conclusions, including the following:

There are no studies, either national in scope or Minnesota-specific, which conclusively show a difference in patient outcomes based on type of anesthesia provider. [page 23, DOH study.] [emphasis added]

4. Centers for Disease Control

In 1990, the federal Centers for Disease Control (CDC) considered undertaking a multimillion-dollar study regarding anesthesia outcomes. Following a review of anesthesia data from a pilot study issued by the CDC and the Battelle Human Affairs Research Centers, however, the CDC concluded that morbidity and mortality in anesthesia was too low to warrant a broader study. The pilot study, published on December 1, 1988, was entitled, "Investigation Of Mortality and Severe Morbidity Associated With Anesthesia: Pilot Study." The pilot study stated that:

To obtain regional estimates of rates of mortality and severe morbidity totally associated with anesthesia with a precision of about 35% a nationwide study consisting of 290 hospitals should be selected. This size study would cost approximately 15 million dollars spread over a 5-year period.

5. National Academy of Sciences Study

This study was mandated by the U.S. Congress and performed by the National Academy of Sciences, National Research Council. The report to Congress stated: "There was no association of complications of anesthesia with the qualifications of the anesthetist or with the type of anesthesia." [House Committee Print No. 36, Health Care for American Veterans, page 156, dated June 7, 1977.]

6. St. Paul Data

The St. Paul Fire and Marine Insurance Company malpractice insurance premium rate for claims-made coverage for self-employed CRNAs decreased nationally a total of 50 percent from 1988 to 2001. The premium drop is detailed in the appendix titled, "Nurse Anesthetist Professional Liability Premiums." At the time the data was compiled, St. Paul was the country's largest provider of liability insurance for health care professionals, and insured both CRNAs and anesthesiologists. In

December 2001, St. Paul announced that it was leaving the medical malpractice business, and would no longer be providing coverage for CRNAs, anesthesiologists, or other healthcare providers. St. Paul's exit from the business was ongoing as this publication went to press. From 1988 to 1996, St. Paul returned nearly \$26,000,000 in premiums to its insured CRNAs because the loss experience was substantially better than St. Paul originally predicted.

The decline in CRNA malpractice insurance premium rates demonstrates the superb anesthesia care that CRNAs provide. The rate drop is particularly impressive considering inflation, an increasingly combative legal system, and generally higher jury awards.

In a 1988 book, Mark Wood of St. Paul Fire and Marine Insurance Company summarized a St. Paul study of its anesthesia-related claims. St. Paul studied the leading medical liability allegations that St. Paul insured anesthesiologists and CRNAs reported between 1981 and 1985. The data consisted of all claims, including pending and closed claims. St. Paul concluded that "[n]urse anesthetist loss experience is very similar to that of anesthesiologists . . ." [Wood, MD, "Monitoring Equipment and Loss Reduction: An Insurer's View," in Gravenstein JS, Holzer JF (eds): *Safety and Cost Contained in Anesthesia*. 1988. Stoneham, Mass.: Butterworth Publishers.]

Clearly, CRNAs enjoyed a tremendous decline in professional liability premiums over a prolonged period. The appendix details premium information from St. Paul for CRNAs, both on a state-by-state basis, and nationally.

Section Two

Anesthesiologist Distortions Concerning Quality of Care

The following section discusses the articles (by Abenstein and Warner; Silber, et al.; and Wiklund and Rosenbaum) that anesthesiologists have primarily cited to support their view that CRNAs should be anesthesiologist supervised, and that utilization of anesthesiologists improves anesthesia outcomes. As the following will demonstrate, however, none of the articles cites any credible scientific evidence that validates the anesthesiologists' position. In fact, two of the four articles do not even discuss the role of CRNAs in anesthesia care.

I. Abenstein and Warner Article in *Anesthesia & Analgesia*

[Abenstein, JP, Warner, MA. "Anesthesia providers, patient outcomes and costs." *Anesthesia & Analgesia*. 1996;82:1273-1283.]

A. Abenstein and Warner Distortions Concerning Minnesota Department of Health Study

The Minnesota Department of Health (DOH) study discussed earlier led to development of the Abenstein and Warner article. In its 1994 study of the provision of anesthesia services by CRNAs and anesthesiologists, the DOH reached four "key findings,"¹ including the following:

There are no studies, either national in scope or Minnesota-specific, which conclusively show a difference in patient

¹ "Limitations on the study made it impossible to fully evaluate the cost of service provided under each type of employment arrangement. However, there are some findings worth noting. Anesthesia providers are paid equivalent amounts per case under Medicare, and will likely under Medicaid, as well, when new guidelines are implemented. Reimbursement is declining to all anesthesia providers for federally funded programs and other third party payers are also beginning to negotiate lower reimbursement rates."

"There are no studies, either national in scope or Minnesota-specific, which conclusively show a difference in patient outcomes based on type of anesthesia provider."

"National and state health care reform are effecting [sic] the entire health care market in Minnesota. Although this study is the result of concerns over the changing market for anesthesia services, the primary forces driving these changes are effecting [sic] all of health care. For more than a decade, rising health care costs have been a major concern for state and federal programs. As both Medicare, and later Medicaid, began to review their payment methodologies to reduce costs, payers and providers were prompted to seek new ways to control costs and, at the same time, maintain or improve the quality of services. Reduced payments by payers have brought about greater competition in many areas, including anesthesia services, and a growth in managed care concepts (i.e., negotiated fees, the formation of provider networks). This has been particularly true in Minnesota."

"As a result of the reduced reimbursement to anesthesia providers and the increased focus on cost containment, Minnesota hospitals have had to examine their budgets and attempt to cut costs. Hospitals began to look for new service delivery models that would encourage the cooperation of providers in their delivery of services, maintain high quality, and be cost effective. Consequently, several hospitals made the decision to terminate their CRNAs from their hospital staff and to contract for services. The providers are thus responsible for the billing and overhead costs, not the hospital, and for providing quality service to the patient. This decision, based on economics and the changing market, provide cost savings to these hospitals. The impact of health care market dynamics will continue as the market demands shift and develop both locally and nationally."

"In summary, anesthesia services continue to be provided primarily in a 'care team' approach using both anesthesiologists and CRNAs, with current risk levels remaining very low. The market and demand for both CRNAs and anesthesiologists is changing and we can expect continued flux in this market for several years." [pages 23-24 of the Minnesota DOH study]

outcomes based on type of anesthesia provider. [page 23, DOH study] [emphasis added]

The Minnesota Society of Anesthesiologists (MSA) had urged the DOH to reach different conclusions, and the department refused to do so. Disappointed that their views about quality weren't reflected in the department's report, anesthesiologists decided to seek a different forum to air their opinions. Two Minnesota anesthesiologists — doctors Abenstein and Warner — essentially repackaged the MSA's report that the MSA had submitted to the DOH, and published it as an article in June 1996 in *Anesthesia and Analgesia*. Abenstein and Warner acknowledge in their article that it "is an abridged version of a document submitted by the Minnesota Society of Anesthesiologists to the Minnesota Commissioner of Health." [page 1273]

The Abenstein and Warner article purported to analyze quality of care in anesthesia, quoted the Minnesota Department of Health report at length at the end of the article, but failed to mention the key conclusion about quality quoted above. It is clear that Abenstein and Warner failed to mention the conclusion because it did not fit their thesis that CRNAs should be anesthesiologist supervised.

As Christine Zambricki states in an article from the October 1996 *AANA Journal*:

We are curious as to how the authors' [Abenstein and Warner] omission of three of the [Minnesota DOH's] four concluding findings could be overlooked in *Anesthesia and Analgesia*'s extensive peer and editorial review. This is especially surprising because the finding that directly contradicts Abenstein and Warner's principal thesis was considered crucial enough to the report to be restated in the report's executive summary. If, as the Minnesota Department of Health's report contends, there are no studies that 'conclusively show a difference in patient outcomes based on type of anesthesia provider,' it becomes difficult, if not impossible, to support the authors' thesis that an increase in the number of practicing anesthesiologists is the primary reason for the decrease in anesthesia-related mortality.

[Zambricki, CS. "Anesthesia providers, patient outcomes, and costs": the AANA responds to the Abenstein and Warner article in the June 1996 *Anesthesia and Analgesia*." *AANA Journal*. 1996;64:413-416, at page 415.]

The Abenstein and Warner article is a partisan advocacy piece — it is not a credible scientific evaluation. Remarkably, despite his subsequent decision to publish the Abenstein and Warner article, the editor of *Anesthesia and Analgesia* (Dr. Ronald Miller), stated that:

There were many reasons not to publish this paper. First, as recognized by Abenstein and Warner, [it] lacks the scientific credibility of a review or original article and is related to policy making more than science'... Abenstein and Warner often are not only subjective, but clearly biased toward one method of anesthesia care delivery.... [Miller, Ronald D., "Perspective from the Editor-in-Chief: Anesthesia Providers, Patient Outcomes, and Costs." *Anesthesia and Analgesia*. June 1996, 82:1117-18.]

B. Abenstein and Warner Distortions Relating to Increased Number of Anesthesiologists and Anesthesia Safety

Abenstein and Warner conclude that improved patient outcomes associated with the administration of anesthetic agents have resulted almost exclusively from the growth of the number of practicing anesthesiologists. In contrast, as noted above, the Minnesota Department of Health concluded that studies to date do not show a difference in patient outcome based on whether the anesthesia provider is an anesthesiologist or CRNA, rejecting the position argued by Abenstein and Warner.

Gross variations between observed reductions in anesthesia-related mortality compiled by Abenstein and Warner and the growth in membership reported by the American Society of Anesthesiologists suggests that there is little, if any, correlation between the reduction in mortality and an increase in anesthesiologists. Increases in the numbers of practicing nurse anesthetists show the same long-term growth as anesthesiologists, and variations in the rate of growth of CRNAs seem to coincide with the variations in the decline of mortality compiled by Abenstein and Warner.

The exponential decline in anesthesia-related mortality has resulted from the almost complete elimination of administrators lacking anesthesia education; improvements in technology and anesthetic agents; a marked increase in the proportion of patients who received anesthesia care from highly educated anesthesia specialists, including anesthesiologists and CRNAs; and an increased understanding of the causes of adverse events associated with anesthesia.

In two different letters to the editor of *Anesthesia & Analgesia*, physicians elaborated on the flaws in Abenstein and Warner's analysis:

1. "It is interesting that there exist no data within the last 20 years concerning patient outcome as a function of anesthesia provider. Much has changed in anesthetic practice in 20 years, not only from the standpoint of medical and technical factors, but also in terms of the distribution of providers, the types of patients and surgeries encountered by these providers, and the organizational nature of

these practices. . . . In summary, although the data, information, and analyses provided by the authors are interesting and provocative, I strongly disagree with their nearly unqualified statement that 'the anesthesia care team and hybrid practices appear to be the safest methods of delivering anesthesia care. This safety may be due, in part, to the rapid availability of physicians, especially during medical crises.' The question of how best to organize anesthesia care (or any other type of medical care) for achieving maximum patient safety has not yet been thoroughly examined. It is inappropriate to make claims such as those made by the authors based on such a paucity of data and analysis." [David M. Gaba, MD, Department of Anesthesia, Stanford University School of Medicine, Veterans Affairs Palo Alto Health Care System, Palo Alto, California; *Anesthesia & Analgesia*. December 1996, 82:1347-1348, Letters to the Editor.]

2. "... I question the validity of the conclusion reached by the authors [Abenstein and Warner] regarding the anesthesia care team in which they state, 'When the data are critically examined, the evidence is very supportive that the anesthesiologist-led anesthesia care team is the safest and most cost effective method of delivering anesthesia care. At this time, public policy decisions should encourage the development of anesthesia care teams where none exist, particularly in the rural areas, and assure the continued utilization of this patient care model' Unchallenged acceptance of the conclusion that evidence supports a specific method of anesthesia care delivery to be the 'safest and most cost effective' is misleading to patients, colleagues, and those responsible for shaping health care delivery policy. . . . the participation of certified registered nurse anesthetists (CRNAs) in delivery of anesthesia care would have ceased many years ago if there was evidence that this participation resulted in a less favorable outcome compared with anesthesia personally administered by an anesthesiologist." [Robert K. Stoelting, MD, Department of Anesthesia, Indiana University School of Medicine, Indianapolis; *Anesthesia & Analgesia*. December 1996, 82:1347, Letters to the Editor.]

C. *Abenstein and Warner Distortions Relating to the Bechtoldt and Forrest Studies*

The report submitted to the Minnesota Department of Health by the Minnesota Society of Anesthesiologists, and the Abenstein and Warner article, rewrote the findings of the Bechtoldt and Forrest studies that we summarized previously. Abenstein and Warner claim that the studies show that there were differences in the outcomes of care based on

type of provider, **notwithstanding that the actual researchers came to the opposite conclusion.**

The Minnesota Department of Health report, in addressing the Bechtoldt study, stated:

Observed differences [in the incidence of anesthetic-related deaths] suggest that anesthesiologists and the CRNA-anesthesiologist care team were somewhat associated with lower rates of anesthesia-related deaths than CRNA's [sic] working alone. However, given the absence of controls, the findings cannot be used to determine (1) whether the differences are greater than would be expected by chance, or (2) the extent that the type of anesthesia provider is responsible for the differences versus other factors. The author concluded that the incidence of patient death among these groups is 'rather similar.' [page 12, Minnesota DOH study]

Concerning the Forrest study, the Minnesota Department of Health stated:

Outcomes considered were deaths, complications, and intermediate outcomes. Ratios of the actual number of adverse outcomes (or deaths, morbidity, or weighted outcome scales) to the number predicted from selected patient and hospital characteristics (i.e., indirectly standardized outcome ratios) for the two groups were compared and tested. The study concluded that, although there were some unadjusted outcome differences between the two groups, after controlling for patient and hospital characteristics, there were no statistically significant differences in outcomes between the two groups of hospitals defined on the basis of primary type of anesthesia provider. [page 11, Minnesota DOH study]

A December 1996 AANA *Journal* article by Denise Martin-Sheridan and Paul Wing, as well as the Zambricki article cited earlier, details the Abenstein and Warner article's numerous distortions and errors. Martin-Sheridan and Wing conclude that:

In general, the authors [Abenstein and Warner] reconfigure statistics and findings in the literature concerning outcomes of anesthesia care based on provider. If the best available research studies did not support their position, we feel it was inappropriate and misleading to reconfigure data upon which recommendations for policy decisions were made.

[Martin-Sheridan, D, Wing, P. "Anesthesia providers, patient outcomes, and costs: a critique." *AANA Journal*. 1996; 64(6):528-534, at page 533.]

2. Silber Study in Medical Care

[Silber, JH, Williams, SY, Krakauer, H, Schwartz, JS. "Hospital and Patient Characteristics Associated With Death After Surgery. A Study of Adverse Occurrence and Failure to Rescue." *Medical Care*. 1992;30:615.]

The Silber study examined the death rate, adverse occurrence rate, and failure rate of 5,972 Medicare patients undergoing two fairly low-risk procedures—elective cholecystectomy and transurethral prostatectomy. The study did not discuss any anesthesia provider except physician anesthesiologists; the study did not even mention CRNAs. The study, therefore, had nothing to do with CRNAs and did not compare the outcomes of care of nurse anesthetists to those of anesthesiologists. The study did not address any aspect of CRNA practice; it certainly did not explore the issue of whether CRNAs should be physician supervised.

The Silber study was a pilot study, i.e., a study to demonstrate the feasibility of performing a more definitive study concerning patients developing medical complications following surgery. It would be inappropriate to formulate public policy based on the Silber study; the study does not address CRNAs, and cannot be considered conclusive even about the issues that it does address. The Silber study states, at page 625:

This pilot project examined ideas that, to our knowledge, have not been examined previously, and more work is needed before the full significance of the results can be determined. It is especially appropriate, therefore, that the limitations of the project be recognized.

At most, the study's conclusions support the proposition that certain facilities would benefit from having a board-certified anesthesiologist in the Intensive Care Unit. This might result in the "rescue" of some patients who have undergone elective cholecystectomies and transurethral prostatectomies and developed life-threatening postoperative complications. The Silber study's conclusions have nothing to do with nurse anesthetists or the nature of who may supervise, direct, or collaborate with nurse anesthetists. At most, the study concluded that anesthesiologists may play a clinically valuable role in caring for postoperative complications. The study, however, did not involve examination of the outcomes of anesthesia in the operating room.

In his analysis of the Silber study, Dr. Michael Pine (physician and expert in quality and health care) stated that:

Thus, the presence of board-certified anesthesiologists does

not appear to lower the rate of complications, either alone or in combination with other factors such as high technology. It is not anesthesia care but the failure to rescue patients once complications occur which contributes to the death rate. On the other hand, unmeasured factors such as a higher percentage of other board-certified physicians in the hospital, also may account for the better outcomes. The conclusion to be drawn from this study is that, although the presence of board-certified anesthesiologists may not make a difference in the operating room, it may make a difference in the failure to rescue patients from death or adverse occurrences after postoperative complications have arisen. This conclusion is in keeping with the expanded role that anesthesiologists have identified for themselves in post-operative care....

Dr. Pine went on to conclude, in pertinent part, regarding the Silber study that:

1. This study encompassed the entire period of operative and postoperative care and was not specific to anesthesia staffing.
2. The rate of deaths possibly attributable to anesthesia care is a negligible fraction of the death rate found in this study.
3. The factors that significantly affect mortality and are most amenable to clinical interventions arise during postoperative management, not during the administration of anesthesia.
4. The type of anesthesia provider does not appear to be a significant factor in the occurrence of potentially lethal complications. If anything, this study suggests that surgical skill is more important.
5. The presence of board-certified specialists does appear to make an important difference in post-surgical care."

Pennsylvania anesthesiologists have unsuccessfully attempted to use the Silber study as a justification for a restrictive regulation they have urged the state's board of medicine to adopt. While the board proposed the regulation, it has not adopted it. Reportedly, the board decided at a March 1998 meeting to withdraw the proposal. The proposed regulation would have required physicians who delegate duties to CRNAs to have qualifications that only anesthesiologists typically possess. The practical effect would have been to require CRNAs to be anesthesiologist supervised in every practice setting.

Significantly, the Independent Regulatory Review Commission (IRRC), a Pennsylvania oversight commission that reviews health care pro-

posals, carefully evaluated the Silber study, and issued a report rejecting the study as any basis for requiring anesthesiologist supervision of CRNAs. The IRRC stated that:

Based on our review of the 1992 *Medical Care* article, we have concluded, as its authors clearly state, it is a preliminary study and that caution should be taken in making any definitive conclusions. More importantly, the authors did not consider the scenario of an operating physician delegating the administration of anesthesia to a CRNA, or what expertise the operating physician should have in order to safely delegate anesthesia to a CRNA. Therefore, we do not believe this study should be used as justification for the significant change in practice for the administration of anesthesia.

The IRRC further stated that:

There have been two studies, both completed over 20 years ago, that compared the outcomes of anesthesia services provided by a nurse anesthetist and an anesthesiologist. Neither of these studies concluded that there was any statistically significant difference in outcomes between the two providers. This conclusion was also reached by the Minnesota Department of Health, which recently completed a study on the provision of anesthesia services. In fact, most studies on anesthesia care have shown that adverse outcomes and deaths resulting from anesthesia has decreased significantly in the last several decades as [a] result of improved drugs and monitoring technology.

3. *New England Journal of Medicine* Articles (by Wiklund and Rosenbaum)

[Wiklund, RA, Rosenbaum, SH. "Medical Progress: Anesthesiology" (part one). *New England Journal of Medicine*. 1997;337(16):1132-1141. Wiklund, RA, Rosenbaum, SH. "Medical Progress: Anesthesiology" (part two). *New England Journal of Medicine*. 1997;337(17):1215-1219.]

These articles attempt to summarize key developments in the broad field of anesthesiology during the past 30 years. The articles focus on "preparation of patients for surgery, recent developments in anesthetic agents and techniques, multimodal pain management, and postoperative complications related to anesthesia."

The articles, however, do not attempt to compare patient outcomes by type of anesthesia provider. In fact, the articles do not discuss the

involvement or contributions of CRNAs. The articles, therefore, have no relevance to the issue of CRNA versus anesthesiologist quality, and certainly have no bearing on the question of whether CRNAs should be physician supervised.

The articles have some merit as an overview of anesthesiology developments during the past 30 years. For example, the authors discuss advances in applied research that have led to new technology, products, and techniques. In certain areas, however, the authors leave the path of an unbiased review of the specialty to make unsubstantiated or misleading comments about the unilateral contributions of anesthesiologists to the advancements achieved.

For example, part one of the article states in its opening paragraph that anesthesia-related deaths have decreased dramatically since the late 1960s, coinciding with a decision by the National Institutes of Health to "support training in clinical anesthesiology." While it makes logical sense that proper training should enhance outcomes in all disciplines, the reader is left to assume that it was this seminal event – physician training in anesthesiology – which has led directly to the decreased mortality rates mentioned.

In fact, many factors, some of which are discussed in the articles, have influenced the trend to improved anesthesia-related outcomes. The articles make little attempt to provide statistical support regarding the causes of outcome trends and do not compare outcomes based upon type of anesthesia provider, type of case, surgical setting, or patient physical status.

The authors make the blanket statement that:

Increasingly, anesthesiologists direct the preoperative assessment and preparation of patients for surgery with the aim of ensuring safe and efficient care while controlling costs by reducing unnecessary testing and preventable cancellations on the day of surgery. [page 1132]

While the value of preoperative patient assessment is indisputable, the authors reference only one article to substantiate their claim that anesthesiologist management of this process is particularly beneficial. In that case study [Fischer, SP. "Development and Effectiveness of an Anesthesia Preoperative Evaluation Clinic in a Teaching Hospital." *Anesthesiology*. 1996;85(1):196-206], cost-savings are reported through the use of an organized preoperative assessment clinic staffed by anesthesiologists and nurse practitioners, a service not previously available at this large, university-based medical center. Consequently,

both nurses and physicians contributed to the clinic's cost effectiveness. Any inferences to be drawn from the Fischer article are limited because the article is based on a case study of a single anesthesia preoperative evaluation clinic. Moreover, the Fischer study did not compare CRNA preoperative evaluation effectiveness with that of anesthesiologists.

The Fischer article points out the benefits of developing protocols for reasonable preoperative testing and evaluation, but breaks no new ground in this area. If anything, the findings indicate that cost effective care in the preoperative period results from multidisciplinary guideline development and acceptance, as opposed to guidelines developed and managed solely by anesthesiologists.

Wilkund and Rosenbaum fail to support their premise that anesthesiologists, as a group, are "increasingly" staffing preoperative clinics and developing their own standardized protocols for assessing patients. In fact, their analysis of the Fischer article suggests there is a trend toward protocols developed by various specialties that can be utilized by all providers caring for the patient in the preoperative period.

Examples referenced in the article include guidelines jointly developed by the American College of Cardiology and the American Heart Association regarding the preoperative cardiovascular evaluation of patients undergoing noncardiac surgery. According to the authors, these guidelines have actually replaced those previously developed and standardized by anesthesiologists.

Further misleading editorial comments appear in part two of the article. Addressing the subject of new techniques of patient monitoring, the authors state:

Prompted by the Harvard Medical School report on standards of monitoring during anesthesia, the American Society of Anesthesiologists has become a leader in the adoption of standards of care and guidelines for practice. As a result, pulse oximetry and capnography (the analysis of carbon dioxide in exhaled air) are now used routinely to monitor general anesthesia in virtually all surgical patients in the United States. [page 1217]

Once again, the authors blend legitimate technological advancement with credit to a single professional group. In fact, the Harvard monitoring standards referenced here were first adopted and promoted by the American Association of Nurse Anesthetists. While it is true that the American Society of Anesthesiologists has since endorsed the standards as well, it is absurd to claim that oximetry and capnography have

anesthesia standards of care solely "as a result" of the ASA's endorsement.

Survey Study in Anesthesiology

Sizer, JH, Kennedy, SK, Even-Shoshan, O, Chen, W, Koziol, LE, Snowan, AM, Longnecker, DE. "Anesthesiologist Direction and Patient Outcomes." *Anesthesiology*. 2000; 93:152-63.]

In September 1998, anesthesiologists began publicizing a scientific abstract titled "Do Nurse Anesthetists Need Medical Direction by Anesthesiologists?" The abstract was published in *Anesthesiology* (1998; 93:152-63), the journal of the American Society of Anesthesiologists. ASA also reported the findings of a study, conducted in Pennsylvania, which compared the outcomes of surgical patients whose anesthesia was directed by anesthesiologists with patients whose anesthesia was directed by other physicians, such as surgeons. The study came to be known as the "Pennsylvania study."

Nearly two years later, the Pennsylvania study was published in the July 2000 issue of *Anesthesiology* with the title, "Anesthesiologist Direction and Patient Outcomes." Reportedly, both the *Journal of the American Medical Association* and the *New England Journal of Medicine* declined to publish the Pennsylvania study, forcing the ASA to publish the study in its own journal if it wanted the study to be published at all. Given the ASA's political agenda and the composition of *Anesthesiology's* editorial board, which is exclusively comprised of more than 40 anesthesiologists, serious questions of objectivity can be raised.

Then, on January 18, 2001, the Health Care Financing Administration (HCFA), which became the Centers for Medicare & Medicaid Services, or CMS, in June 2001 published a 14-page anesthesia rule in the *Federal Register* (Vol. 66, No. 12, pp. 4674-87) that affirmed, in no uncertain terms, AANA's contention that the Pennsylvania study is not relevant to the issue of physician supervision of nurse anesthetists. The January 18 rule was rescinded on November 13, 2001, with the publication of a new rule that allows state governors to write to CMS and opt out of the federal physician supervision requirement after meeting certain conditions. The January 18 rule's extensive comments supportive of nurse anesthetists and dismissing the relevancy of the Pennsylvania study to the supervision issue, however, have in no way been repudiated by CMS and still remain part of the public record.)

On its surface, the study suggests that patient outcomes are better when nurse anesthetists are directed by anesthesiologists. However, a closer examination clearly reveals that the study

- is not about anesthesia care provided by nurse anesthetists
- actually examines post-operative physician care.

A. Background

The study was conducted using data obtained from Health Care Financing Administration (HCFA) claims records. The study group consisted of 217,440 Medicare patients distributed across 245 hospitals in Pennsylvania who underwent general surgical or orthopedic procedures between 1991-94. Dr. Silber headed a research team that included three anesthesiologists.

B. Study Does Not "Compare Anesthesiologists Versus Nurse Anesthetists"

According to Dr. Longnecker, one of the anesthesiologist researchers: "The study ... does not explore the role of (nurse anesthetists) in anesthesia practice, nor does it compare anesthesiologists versus nurse anesthetists. Rather, it explores whether anesthetists provide value to the delivery of anesthesia care." (Source: Memorandum from Dr. Longnecker to Certified Registered Nurse Anesthetists in University of Pennsylvania Health System's Department of Anesthesia, October 5, 1998)

Why, then, was such a misleading title ("Do Nurse Anesthetists Need Medical Direction by Anesthesiologists?") chosen for the abstract? The answer: *for political reasons*. Consider these facts:

- The abstract was published in the midst of the controversy between anesthesiologists and nurse anesthetists over HCFA's proposal to remove the physician supervision requirement for nurse anesthetists in Medicare cases.
- The study was funded in part by a grant from the American Board of Anesthesiology, which is affiliated with the ASA. ASA vehemently opposes HCFA's proposal.

Why was the name of the abstract changed prior to publication of the paper in the July 2000 issue of *Anesthesiology*? Most likely for the following reasons:

- As Dr. Longnecker stated in his memorandum, the study was not intended to examine the question posed by the abstract's title.
- The study clearly could not and did not answer the question posed by the abstract's title.
- Pressure from AANA in the form of statements to the media and commentary published on the Internet forced the researchers and ASA to rename the paper for publication.

C. Problems with the Data

Careful examination of the "findings" reported in the paper reveal numerous problems.

Glaring Admissions. In the next to last paragraph of the paper, the researchers conclude that, "Future work will also be needed to determine whether the mortality differences in this report were caused by differences in the quality of direction among providers, the presence or absence of direction itself, or a combination of these effects." Boiled down, *this clearly is an admission by the researchers that the study does not, in fact, prove anything about the effect—positive or negative—of anesthesiologist involvement in a patient's overall care, let alone the patient's anesthesia care!*

This statement appears in a section titled "Discussion," which is devoted primarily to explaining away the limitations of the billing data used (HCFA's claims records comprise a retrospective database intended for billing purposes, not quality measurement) and the myriad adjustments for variables which the data required the researchers to make. According to the researchers, among other adjustments were those made for severity of illness and the effect of hospital characteristics.

The researchers, however, admit the following:

- "The accuracy of our definitions for anesthesiologist direction (or no direction) is only as reliable as the bills (or lack of bills) submitted by the caregivers."
- "We cannot rule out the possibility that unobserved factors leading to undirected cases were associated with poor hospital support for the undirected anesthetist and patient."
- "...if anesthesiologists had a tendency not to submit bills for patients who died within 30 days of admission, our results could be skewed in favor of directed cases."

These admissions by the researchers seriously limit the application of the data. They are also proof that ASA's use of data from this study, in advertising campaigns and lobbying efforts to discredit nurse anesthetists and frighten seniors, has been opportunistic, misleading, and ethically reprehensible at best.

Time Frame. Nurse anesthetists do not diagnose or treat nonanesthesia postoperative complications—they administer anesthesia. According to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), anesthesia mishaps usually occur *within 48 hours of surgery*. The study, however, evaluated death, complication,

and failure to rescue rates *within 30 days of admission*, encompassing not only the time period of the actual surgical procedures, but also a substantial period of postoperative care as well. Therefore, it is impossible to know from the data how many or what percentages of deaths, complications, and failures to rescue occurred within that 48-hour window and were directly attributable to anesthesia care. However, if one considered the study's sample size (217,440) in relation to the widely accepted anesthesia mortality rate of one death in approximately 240,000 anesthetics given, which is recognized by ASA, AANA and cited in the Institute of Medicine report, *To Err is Human: Building a Safer Health System* (Kohn LT, Corrigan JM, Donaldson MS, Washington, DC: National Academy Press, 1999.), logic would dictate that less than a single individual in the entire database is likely to have died as the direct result of an anesthesia mishap!

What that leaves is this: *Based on the 30-day time frame, it is clear that the study actually evaluates postoperative physician care, not anesthesia care.*

Death Rates. The Pennsylvania study cites death rates that were many times more than the anesthesia-related death rates commonly reported in recent years, again leading one to conclude that the increase was almost certainly due to nonanesthesia factors.

In a June 2000 press release about the Pennsylvania study, the ASA stated "that patient safety has greatly improved from one [death] in 10,000 anesthetics to one in 250,000 anesthetics." (This amounts to four deaths in one million.) In the same press release, the ASA stated that, "Dr. Silber's findings show that for every 10,000 patients who had surgery, there were 25 more deaths if an anesthesiologist did not direct the anesthesia care." Through a complex series of calculations, the difference translates to 8,000 deaths in one million. Thus, the difference in mortality rates that the ASA cited is **2,000 times** the mortality rate ever attributed (including by the ASA) in the last decade to the administration of anesthesia. To attribute a difference of this magnitude solely to the supervision of CRNAs is ridiculous. In actuality, the large differences in mortality and failure-to-rescue are due to differences unrelated to the administration of anesthesia and outside the scope of practice of CRNAs, whether unsupervised, supervised by anesthesiologists, or supervised by other physicians.

Further, it has been noted by Dr. Michael Pine, a board-certified cardiologist widely recognized for his expertise in analyzing clinical data to evaluate healthcare outcomes, that after adjusting the death rates for case mix and severity, *the patients whose nurse anesthetists were su-*

perised by nonanesthesiologist physicians were about 15% more severely ill than the patients whose nurse anesthetists were supervised by anesthesiologists. The paper provides no information to explain why the anesthesiologist-supervised cases involved less severely ill patients.

Dr. Pine's analysis of the study also reveals the following:

1. 7,665 patients (3.5%) died within 30 days of surgery.
2. Although the study found 258 more deaths of patients who may not have had an anesthesiologist involved in their case, the researchers' adjustments for differences among patients and institutions reduced the number by 78% (to 58 deaths).
3. The 58 "excess" deaths could be due to numerous, equally plausible factors, for example:
 - A. Faulty design of the study
 - B. Inaccurate or incomplete billing data (e.g., most of the 23,010 "undirected" cases used had no bill for anesthesia care)
 - C. Unrecognized differences among patients (e.g., medical information on patients' bills was insufficient to permit complete adjustment for their initial risks)
 - D. Unrecognized differences in institutional support (e.g., information about hospital characteristics was inadequate to permit full assessment)
 - E. Medical care unrelated to anesthesia administration (e.g., postoperative medical care provided by anesthesiologists or by other medical specialists who are more likely to be at hospitals in communities where anesthesiologists are plentiful)

The end result is a statistically insignificant difference in negative outcomes between anesthesiologist-directed and nonanesthesiologist-directed cases.

Complication Rates. After adjusting for case mix and severity, *the study found no statistically significant difference in complication rates when nurse anesthetists were supervised by anesthesiologists or other physicians.* Dr. Pine noted that poor anesthesia care is far more likely to result in significant increases in complication rates than in significant increases in death rates. Therefore, Dr. Pine concluded that *this finding strongly suggests that medical direction by anesthesiologists did not improve anesthesia outcomes.*

Failure to Rescue. For the most part, failure to rescue occurs when a physician is unable to save a patient who develops nonanesthesia complications following surgery. Therefore, it is not a relevant measure

of the quality of anesthesia care provided by nurse anesthetists. It is a relevant measure of postoperative physician care, however.

Patients Involved in More than One Procedure. For reasons not explained in the abstract, patients involved in more than one procedure were assigned to the nonanesthesiologist physician group if for any of the procedures the nurse anesthetist was supervised by a physician other than an anesthesiologist. It is impossible to measure the impact of this decision by the researchers on the death, complication, and failure to rescue rates presented in the abstract.

To emphasize the importance of this, consider the following hypothetical scenario: A patient is admitted for hip replacement surgery. A nurse anesthetist, supervised by the surgeon, provides the anesthesia. The surgery is completed successfully. Three days later the patient suffers a heart attack while still in the hospital and is rushed into surgery. This time the nurse anesthetist is supervised by an anesthesiologist. An hour after surgery, and for reasons unrelated to the anesthesia care, the patient dies in recovery. According to the researchers, a case such as this would have been assigned to the nonanesthesiologist group!

Patients Who Were Not Billed for Anesthesia Services. As noted in the discussion on death rates, most of the "undirected" cases had no bill for anesthesia care. The actual figure is 14,137 patients, or 61% of the 23,010 patients defined as undirected. The researchers' flimsy rationale for lumping all nonbilled cases in the undirected category is as follows: "The 'no-bill' cases were defined as undirected because there was no evidence of anesthesiologist direction, despite a strong financial incentive for an anesthesiologist to bill Medicare if a billable service had been performed" (emphasis added). Of course, one might ask how many of those cases were not billed because an anesthesiologist had a bad patient outcome.

Referenced Studies. The researchers claim that their research "results were consistent with other large studies of anesthesia outcomes." Interestingly, the two studies cited were by Bechtoldt (refer to page 3 of this publication) and Forrest (refer to page 4 of this publication). As indicated below, neither of these studies agrees with the conclusions reached by Dr. Silber and his team of researchers on the Pennsylvania study:

- Bechtoldt reported that the Anesthesia Study Committee (ASC) of the North Carolina Medical Society "...found that the incidence among the three major groups (the CRNA, the anesthesiologist, and the combination of the CRNA and anesthesiologist) to be rather similar. Although the CRNA working alone accounted for

about half of the anesthetic-related deaths, the CRNA working alone also accounted for about half of the anesthesiologists administered."

- After applying statistical tests to the results of research conducted by the Stanford Center for Health Care Research, Forrest stated: "Thus, using conservative statistical methods, we concluded that there were no significant differences in the outcomes between the two groups of hospitals defined by type of anesthesia provider. Different methods of defining outcome changed the direction of differences for two weighted morbidity measures."

Forrest's supporting the argument that other studies do not agree with the reported findings of Silber and his fellow researchers is the following objective, third-party opinion offered by HCFA/CMS in the Federal Register on January 18, 2001: Our decision to change the Federal requirement for supervision of CRNAs applicable in all situations is, in part, the result of our review of the scientific literature which shows no overarching need for a Federal regulation mandating any model of anesthesia practice, or limiting the practice of any licensed professional" (p. 4685-4686)

HCFA/CMS Affirms that Study Not About CRNA Practice

In the anesthesia rule published in the January 18, 2001, Federal Register by HCFA/CMS, the administration dismissed all claims by ASA and the Pennsylvania study research team that the study examined CRNA practice and was relevant to the supervision issue. HCFA/CMS stated the following:

- "We have also reviewed a more recently published article by Dr. Silber (July 2000) and colleagues from the University of Pennsylvania. This article also is not relevant to the policy determination at hand because it did not study CRNA practice with and without physician supervision, again the issue of this rule. Moreover, it does not present evidence of any inadequacy of State oversight of health professional practice laws, and does not provide sound and compelling evidence to maintain the current Federal preemption of State law." (p. 4677)
- "One cannot use this analysis to make conclusions about CRNA performance with or without physician supervision." (p. 4677)
- "Even if the recent Silber study did not have methodological problems, we disagree with its apparent policy conclusion that an anesthesiologist should be involved in every case, either personally performing anesthesia or providing medical direction of CRNAs." (p. 4677)

Although the January 18 rule was rescinded on November 13, 2001, with the publication of a new rule that allows state governors to write to CMS and opt out of the federal physician supervision requirement after meeting certain conditions, the January rule's extensive comments supportive of nurse anesthetists and dismissing the relevancy of the Pennsylvania study to the supervision issue have in no way been repudiated by CMS and still remain part of the public record.

E. Conclusions

The following conclusions can be drawn from a careful examination of the study "Anesthesiologist Direction and Patient Outcomes":

- The study described has nothing to do with the quality of care provided by nurse anesthetists.
- The study examines postoperative physician care, not anesthesia care.
- The researchers so much as admit that the study does not prove anything with regard to the effect of anesthesiologist involvement in patient care.
- The timing of the publication in the ASA's own journal was politically motivated.
- HCFA/CMS finds no credence in ASA and Dr. Silber's assertions regarding the results of the Pennsylvania study.

Summary

This publication has demonstrated that CRNAs provide superb anesthesia care, and has refuted anesthesiologist contentions to the contrary. Anesthesia-related accidents are infrequent; those that do occur tend to result from lack of vigilance rather than the level of education of the provider. The federal Centers for Disease Control has considered conducting a large-scale study on anesthesia care, but decided such a study would not be worth the high cost such a study would entail. The reason is that the evidence is overwhelming that anesthesia care is very safe, regardless of whether the care is given by a CRNA or anesthesiologist. It is clear that studies to date demonstrate that there is no statistically significant difference between the anesthesia care provided by CRNAs working alone, CRNAs working with anesthesiologists, or anesthesiologists providing care alone. In addition, malpractice insurance premiums (as shown by St. Paul Fire and Marine Insurance Company statistics) for CRNAs decreased significantly from 1988 to 2001, further demonstrating that CRNAs provide safe anesthesia care.

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APPENDIX

Nurse Anesthetist Professional Liability Premiums Premium Changes from 1988 to 2001 (St. Paul Documentation)

State	1988 Premium	2001 Premium	Overall Change (%)
Alabama	2,537	1,716	-821 (-32)
Alaska	2,603	1,097	-1,506 (-58)
Arizona	5,414	3,149	-2,265 (-42)
Arkansas	1,196	1,560	364 (30)
California	7,148	3,258	-3,890 (-54)
Colorado	2,461	1,853	-608 (-25)
Connecticut	4,704	1,312	-3,392 (-72)
Delaware	2,689	2,029	-660 (-25)
D.C.	3,032	2,027	-1,005 (-33)
Florida	3,588	1,993	-1,595 (-44)
Georgia	2,219	1,226	-993 (-45)
Hawaii (1)	2,600	1,816	-784 (-30)
Idaho	4,221	1,640	-2,581 (-61)
Illinois	6,989	2,647	-4,342 (-62)
Indiana	5,809	1,325	-4,484 (-77)
Iowa	3,317	1,608	-1,709 (-52)
Kansas	3,272	1,471	-1,801 (-55)
Kentucky	2,972	1,659	-1,313 (-44)
Louisiana	3,358	2,110	-1,248 (-37)
Maine	2,598	1,286	-1,312 (-51)
Maryland	2,921	1,593	-1,328 (-45)
Massachusetts	2,678	1,164	-1,514 (-57)
Michigan	4,980	1,509	-3,471 (-70)

Minnesota	2,989	699	-1,670 (-70)
Mississippi	2,198	1,213	-985 (-45)
Missouri	7,806	2,738	-5,068 (-65)
Montana	3,872	1,324	-2,548 (-66)
Nebraska	2,228	960	-1,268 (-57)
Nevada	8,231	3,226	-5,005 (-61)
New Hampshire	2,530	1,817	-713 (-28)
New Jersey	5,013	3,013	-2,000 (-40)
New Mexico	2,249	2,522	273 (12)
New York	6,061	3,902	-2,159 (-36)
North Carolina	1,476	1,095	-381 (-26)
North Dakota	2,461	832	-1,629 (-66)
Ohio	5,392	2,638	-2,754 (-51)
Oklahoma	2,309	2,014	-295 (-13)
Oregon	5,737	1,782	-3,955 (-69)
Pennsylvania	1,771	905	-866 (-49)
Rhode Island	3,412	1,357	-2,055 (-60)
South Carolina	1,935	671	-1,264 (-65)
South Dakota	2,736	1,007	-1,729 (-63)
Tennessee	2,352	1,357	-995 (-42)
Texas	2,865	3,319	454 (16)
Utah	3,876	1,578	-2,298 (-59)
Vermont	2,330	1,042	-1,288 (-55)
Virginia	1,431	1,314	-117 (-8)
Washington	2,687	1,716	-971 (-36)
West Virginia	2,592	1,328	-1,264 (-49)
Wisconsin	2,744	889	-1,855 (-68)
Wyoming	3,947	2,126	-1,821 (-46)
TOTAL	177,916	89,437	88,479 (50%)

(1) St. Paul did not provide coverage in Hawaii until 1990